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THERAPEUTIC EVALUATION OF BADRANJBOYA (*MELISSA OFFICINALIS*) IN FASADE TASHAHHUM FID DAM (*DYSLIPIDAEMIA*) IN COMPARISON TO ATORVASTATIN- A RESEARCH ARTICLE

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ABSTRACT

There is no doubt that dyslipidaemia is one of the most common risk factor of cardio vascular diseases. This vulnerable disease is essentially an abnormal concentration of lipids or lipoproteins in blood. Increased level of cholesterol is responsible for atherogenesis, which ultimately leads to development of cardiovascular, cerebro vascular and peripheral vascular diseases. This disease has a significant contribution towards mortality and morbidity rates and also poses economic downfall among patients. These days the treatment of dyslipidaemia is lipid lowering agents with life style intervention, while lipid lowering agents are producing various side effects. In Unani system of medicine several drugs are being used as lipid lowering agents, which are comparatively safe. However, such drugs are still not validated on scientific parameters. Two different drugs were selected and present study contemplated as "Therapeutic evaluation of Bādranjboya (Melissa officinalis) In Fasāde Tashahhum Fid Dam (Dyslipidaemia) In Comparison to Atorvastatin" Thus, a clinical trial was conducted with the objective of providing safe and effective drug in the management of dyslipidaemia.

KEYWORDS: Dyslipidaemia; Melissa officinalis; Bādranjboya.

I. INTRODUCTION & HISTORY OF DYSLIPIDAEMIA

The term "Dyslipidaemia" came into existence as disorder in 20th century. In ancient Unani literature there is no description of any disease by the name of Dyslipidaemia (Fasāde Tashahhum Fid Dam) because in that time the facility of biochemical analysis of blood was not available, so it was not easily detected term. In the light of Unani literature, many Unani physicians and scholars have briefly described under the name of "Simane mufrit" which is almost similar to Dyslipidaemia in all aspects as for as etiology, clinical features, complications, and management is concerned.

The first physician Hippocrates (460-377B.C) the father of Medicine, who described the Simane mufrit as a disease in detail in his famous Unani books 'Fusoole Buqrat' Abzemiya' 'Tabiyatul Insaan' and Hifz-ul-sehat. Galen writes in reference to Hippocrates in fusoole Buqrat mai Talkhees Jaleenoos "an Simane mufrit person dies earlier in comparison to lean or thin individuals".[30] Galen (130-200A.D) the Roman pioneer of Unani system of Medicine described, when a person attains extreme of Simane mufrit then his death can occur suddenly due to the ruptureof any major blood vessels of his body, He also told the importance of evacuation (Istifragh) in the treatment of Simane mufrit.[30] Hunnain bin Ishaq (769-873A.D) also gave some important knowledge regarding the management of Simane mufrit. Ali bin Rabban Tabri (810 A.D) has described this disease in detail in 'Firdosul Hikmat'. Abu Bakr bin Mohammad Zakaria Razi (860-925A.D) has described about the Simane mufrit in very detailed manner over sixty pages in his famous book 'Al Havi Fit-Tib' in Volume-6. He explained the importance of Dietotherapy in the management of Simane mufrit.

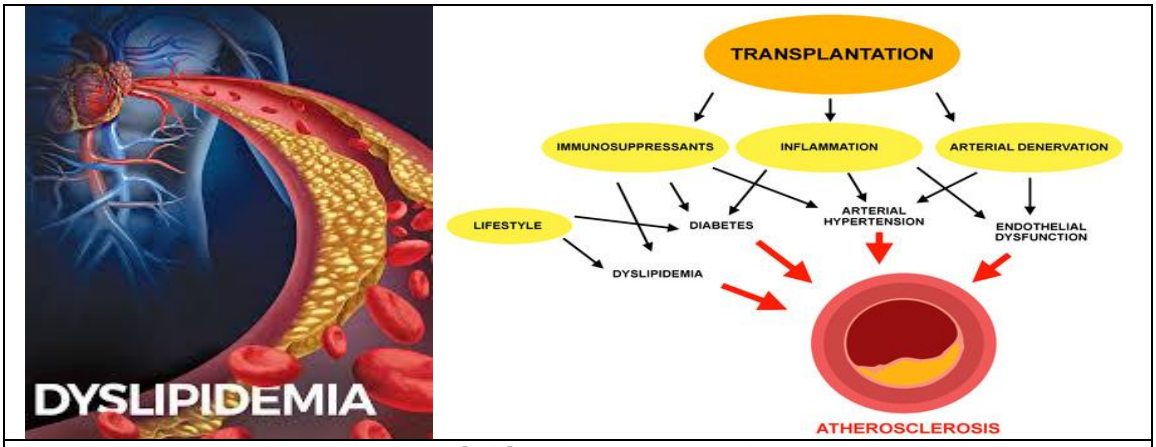

Fig. 01 Dyslipidaemia- A common Disease.

He also shares experiences regarding Simane mufrit and told "pulses and vegetables reduce Simane mufrit because of their low calorific value. Ali Ibne Abbas Majūsi (930-994 AD), pointed out that Saudae Muhtariqa leads to Yabūsat, which causes Salabat (stiffness) in vessels. Ibn-e-Sina (980-1037AD), elucidated that Yaboosat is an important cause of Salabate Nabz.[6] Ibn-e-Zuhr (1092-1162 AD), stated that Hardness in the Nabz develops due to Yaboosat because it eliminates Ratoobat, hence the properties of easy relaxation and contraction of Nabz is decreased.

Cardiovascular risk	Risk factors	Upper target level of plasma LDL–C concentration
Low	• SCORE <1%	3.0 mmol/L (116 mg/dL)
Moderate	• SCORE 1–5% • Young patients (T1DM <35 years; T2DM <50 years without other RF)	2.6 mmol/L (100 mg/dL)
High	• SCORE >5% and <10% • Markedly elevated RF (TC >310 mg/dL (8 mmol/L) or LDL–C >190 mg/dL (4.9 mmol/L) • BP >180/110 mmHg • FH without other major risk factors • Moderate CKD (eGFR 30–59 mL/min) • DM >10 years or additional RF, w/o target organ damage	1.8 mmol/L (70 mg/dL)
Very high	• SCORE ≥10% • ASCVD • FH with ASCVD or with another major RF • severe CKD (eGFR <30 mL/min) • DM & target organ damage	1.4 mmol/L (55 mg/dL)

Fig. 02 Risk factor of Dyslipidaemia.

The word dyslipidaemia is derived from Greek word the etymology; Dys, Difficult and haima, blood, so dyslipidaemia is defined as any abnormality in or abnormal amount of lipid and lipoprotein in blood. Any defect in lipoprotein metabolism, e.g. increased cholesterol, triglyceride, LDL cholesterol and decreased HDL cholesterol. Elevation in one or more of the lipoprotein fractions constitutes hyperlipoproteinemia, some authors used the term hyperlipidaemia or dyslipidaemia instead of hyperlipoproteinemia.

II. Classification of Dyslipidaemia

Siman-e-mufrit (Obesity) has been classified by Al-Razi into two groups in Unani classicalliterature.

- Maqami (Local)
- Umoomi (General)

Maqami Simane Mufrit (Local) Obesity: A When Shaham (Fat) deposit in a particular organ or region then it is called local obesity, for example protrusion of abdomen or breast due to the deposition of fat. Umoomi Simane Mufrit (General Obesity): When generalized deposition of fat occurs in the body then it is called general obesity. In classical Unani literature, no concept of Dyslipidaemia exists as such; but in many cases, it has been described as a disorder. As far as the presence of fat (Lipids) is concerned in blood, Ibn-e-Sina a great Unani philosopher has reported its existence in blood, produced from "Dosoomat Al-Dam". Dosoomat" means "fatty, oily" and "Dam" means "blood". Dosoomat of

blood or the oily substance could be the lipids but as the biochemical analysis of blood was not available at that time so, he could not describe it as per modern parameters.

III. Etiology of Dyslipidaemia (Asbāb)

Following are the causes of Fasāde Tashahhum Fid Dam (Dyslipidaemia) which have been described by the various Unani Physicians.

- Khilqi and Mauroosi (Hereditary and Congenital)
- Kasrate Farhat wa Musarrat (Excess of joy)
- Rahat wa Sakoon (Excessive rest and lack of exercise)
- Excessive use of Martoob wa Duhuniyat (excessive use of fatty diet and oils)
- Kasrate ghiza (excessive eating)
- Baroodate Mizaj (Cold Temperament)
- Kasrate Sharab noshi (excessive consumption of alcohol)
- Excessive sleeping.

Some various causes, which produce buroodat, are as follows.

- Excessive activity disperses the innate heat
- Excessive repose which produce cold by suppressing the innate heat
- Cold food and drinks
- Marked reduction in food
- Cold medicine
- Occupation which produce cold
- Excessive depletion by involving loss of the material for innate heat and dispersionof vital force

IV. Risk Factors for Dyslipidaemia

- Age: Cholesterol levels increase with age. Total cholesterol increases, on the average, more than 2 mg/dL per year during early adulthood and continues increasing but at a lesser rate until age 65, after which it declines slightly.
- Gender: Men have higher total cholesterol levels than women until age 50 and an approximately two-fold higher risk of developing CHD. Women carry a higher proportion of cholesterol in the form of HDL cholesterol.
- Genetic Factors: Primary lipid disorders arising from a monogenic (single gene) abnormality account for only a small fraction of patients with hyperlipidaemia. These relatively uncommon genetic disorders are, however, frequently responsiblefor the most severe hyperlipidaemia.

Fig. 03: Blood lipid profile test for Dyslipidaemia.

- Diet: A diet high in saturated fatty acids raises total and LDL cholesterol. Caloric excess resulting in obesity has more of an effect on triglycerides than on cholesterol. Alcohol has little effect on total cholesterol levels, but it can cause an acute rise in triglycerides among people with hypertriglyceridemia. Moderate alcohol ingestion also causes a rise in HDL levels.
- Medications: Antihypertensive agents that adversely affect lipid levels can compromise the effort to reduce CHD risk. Thiazides temporarily increase LDL cholesterol, when it taken in full doses. Beta-blockers cause modest reductions in HDL cholesterol. Exogenous oestrogens increase HDL2 and can cause extreme triglyceride increases in patients with hypertriglyceridemia. Corticosteroids and HIV protease inhibitors can also dramatically elevate serum lipids. Cigarette / Tobacco Smoke: Smoking increases both the chance of developing atherosclerosis and the chance of dying from coronary heart disease. Passive smoking may also increase risk.
- Obesity: Excess weight increases the strain on the heart and increases the risk of developing Dyslipidaemia even if no other risk factors are present.

V. Introduction of Melissa officinalis

The drug Bādranjboya consists of dried leaves of Melissa officinalis Linn. It is aperennial plant, which belongs to the family of Labiate (Lamiaceae).[139] It is mostly cultivated in Mediterranean region and native to Europe, Northern Africaand West Asia.

In India the plant is found in hilly areas of Punjab, Kashmir, Bengal, Bihar, Kumaon, Rajasthan, Deccan, and Konkan. It occurs during winterseason.It is called lemon balm, bee balm, Melissa, sweet balm. It has a lemony flavour and fragrance. Traditionally this herb was used for longevity, Dyslipidaemia, healing wound, relaxing the heart, treating tooth ache, nowadays it is used in anxiety, mild depression, restlessness, irritability, indigestion, acidity, nausea, bloating and colicky pains, and cold sores. It is also called as a hormonal herb due to its anti-thyroid activity.

Fig. 05 Bādranjboya herb for Dyslipidaemia.

Bādranjboya is a grass fragrant, greenish black and bitter in nature. It is called as Billi Lotan because the cat loves to play on it. It is of two types: i. Shorter species whose leaves are short, light and thin, and its edges are protruded and it has many bands as teeth of the saw, its flowers are bluish red in colour and many times it is cooked as a vegetable. It usually blooms in Mausam-e-Rabeeh (Spring season), its root does not branch. Its seeds resemble seeds of Alsi but are smaller than that and colour is brownish this type is called as Utarjiya and Turanjan, ii. Bigger species, fragrance is same as that of smaller species but much stronger and its leaves are not long but round, colour is greenish on rubbing it gives smell of lemon and leaves resemble like that of Jungli Tulsi. Some Researchers have stated that its leaves are rough, broad and appear same as that of Nana/Pudina (Mentha piperita) Its root gives many branches and flowers are white in colour and according to some colour is bluish white and seeds are very less. its seeds are equal to that of Isapghol (Plantago ovata), its colour is blackish and has fragrance it is usually found in damp areas its potency is same as that of "Farasiyoon" and is said that it is a type of 'Raihan'.

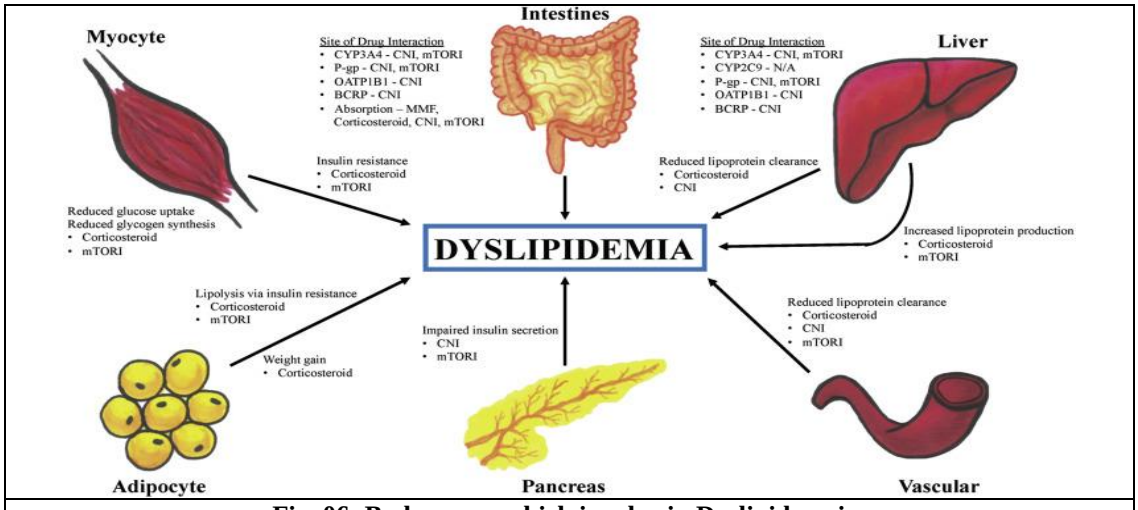

Fig. 06: Body organ which involve in Dyslipidaemia.

VI. METHODOLOGY

The present clinical study entitled as "Therapeutic evaluation of Bādranjboya (Mellisa Officinalis) In Fasāde Tashahhum Fid Dam (Dyslipidaemia) in Comparison to Atorvastatin" has been conducted at the Department of Mo'alajat in Regional Research Institute of Unani Medicine (RRIUM), University of Kashmir, Srinagar. Before get on the patients, all-inclusive protocol was draw up to seek the ethical clearance for bio medical research from Institutional Ethical Committee of the RRIUM. IEC number RRIUM/KU/2018-19/Tech/IEC dated 29.03.2019 and having Clinical Trial Registry- India (CTRI) reference number REF/2020/07/035404 dated 25.07.2020. Apart from clinical examination with detailed history of the disease and necessary haematological, biochemical investigations, Clinical symptoms, history and investigations were recorded on the prescribed Case Report Form (CRF) designed for the study with specific inclusion criterion. After the ethical clearance, clinical study was started by enrolling eligible patients into test and control groups by randomisation with the help of computer generated method from the OPD of Regional Research Institute of Unani Medicine (RRIUM) Hospital. This study was stretched between September 2019 to December 2020.

VII. Criteria for selection of subject

A. Inclusion Criteria

- Diagnosed patients of Dyslipidaemia.
- Patients irrespective of gender
- Total Cholesterol> 240mg /dl
- Triglycerides < 499 mg / dl (High)
- LDL160-189 mg / dl
- HDL< 40 mg / dl in men and <50 in woman
- Age group between 20-50 years of age
- Patients able to participate in the study who follow the protocol
- Known cases of DM type -II with Dyslipidaemia
  - Fasting blood sugar (FBS) > 126 mg/dl - < 150mg/dl
  - Post Prandial blood sugar (PPBS)> 140 mg/dl - < 250mg/dl[3]
- Normotensives (< 130 – 80 mm of Hg)
- Patients who follow the protocol

B. Subjective Parameters

- Palpitation
- Breathlessness
- Joint pain

C. Objective Parameters

- Lipid Profile
- Total Cholesterol
- Triglycerides
- Low Density Lipoprotein (LDL)
- High Density Lipoprotein (HDL)

VIII. RESULT AND DISCUSSION

Table 1: Showing distribution of patients as per Dietary habit

Dietary habit	Test		Control		p-value
	No.	%age	No.	%age	
Mixed	17	85	20	100	0.2310
Vegetarian	3	15	0	0	
Total	20	100	20	100	
Test applied: Fisher exact test					

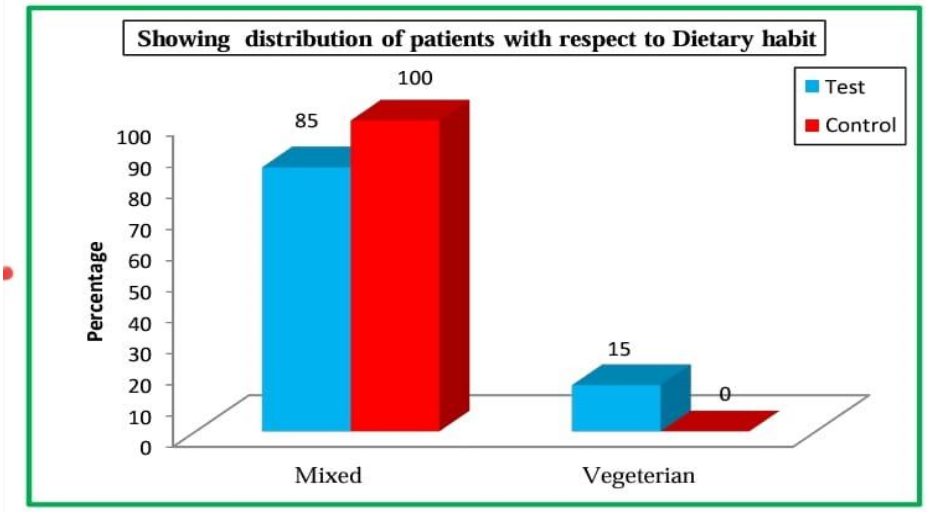

Table 2: Showing distribution of patients with respect to Mizaj					
Mizaj	**Test**		**Control**		**p value**
	No	**%**	**No.**	**%**	
Damvi	6	30	8	40	0.5970
Balgami	7	35	8	40	
Safravi	5	25	4	20	
Saudavi	2	10	0	0	
Total	20	100	20	100	
Test applied: Fisher exact test					

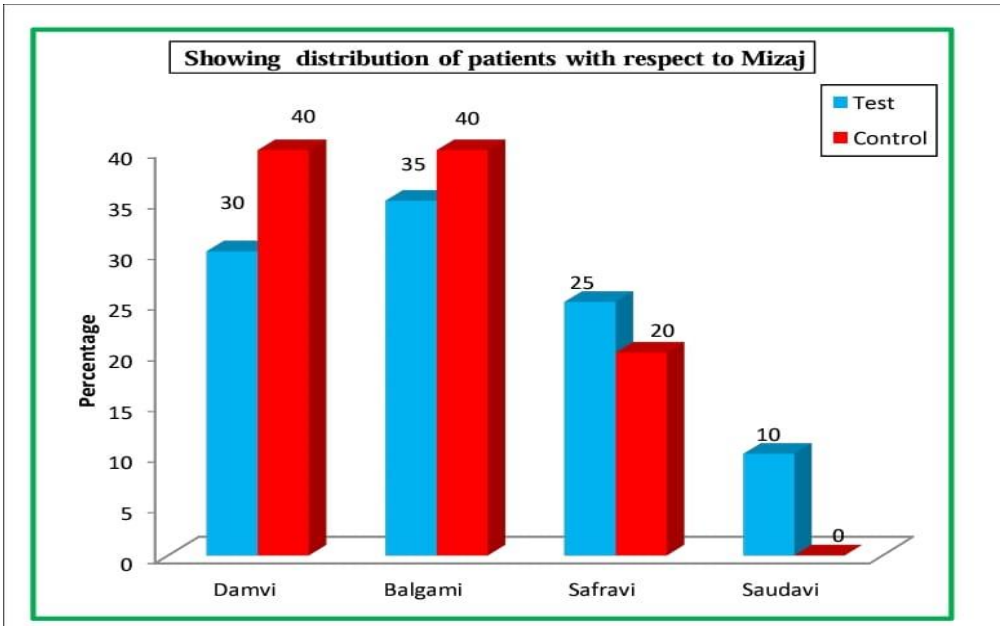

Table 3: Showing distribution of patients as per Breathlessness in Test and Control group									
Status of Breathlessness	**Test**				**Control**				**P value between Groups**
	BT		**AT**		**BT**		**AT**		
	No.	%age	No.	%age	No.	%age	No.	%age	
Normal	0	0	19	95	0	0	18	90	5.48
Mild	0	0	1	5	0	0	2	10	
Moderate	2	10	0	0	2	10	0	0	
Severe	18	90	0	0	18	90	0	0	
Total	20	100	20	100	20	100	20	100	
P-value within Groups	<0.001*				<0.001*				

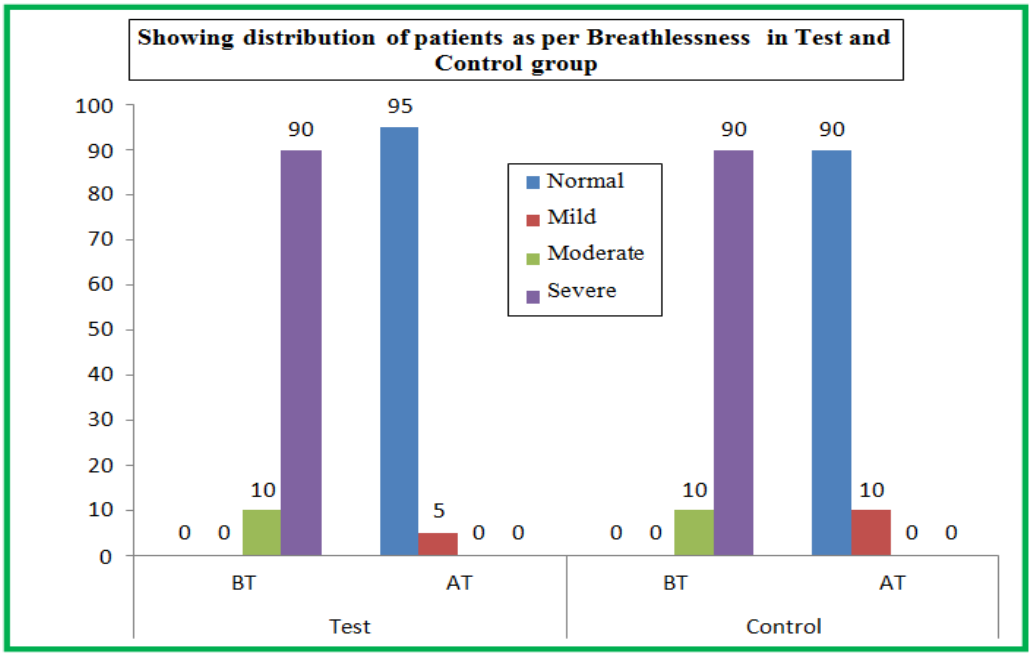

Table 4: Comparison between Test and Control group on base line and after the treatment with respect to Joint pain					
Subjective Parameters	**Group**	**N**	**Mean**	**Std. Deviation**	**p value**
Joint Pain BT	Test Group	20	4.35	1.09	0.346
	Control Group	20	4.05	0.89	
Joint Pain AT	Test Group	20	1	0	-
	Control Group	20	1	0	
Student's independent t-test					

Table 5: Comparison of Joint pain before and after the treatment with in Test and Control group.					
Group	**ollow-up**	**Mean**	**N**	**Std. Deviation**	**p value**
Test	BT	4.35	20	1.08942	<0.001
	AT	1	20	0	
Control	BT	4.05	20	0.88704	<0.001
	AT	1	20	0	

Table 6: Comparison between Test and Control group with respect toObjective parameters					
Objective Parameters	**Group**	**N**	**Mean**	**Std. Deviation**	**p value**
Sr. Chol. BT	Test Group	20	174.95	48.63	0.745
	Control Group	20	179.50	38.79	
Sr. Chol. AT	Test Group	20	182.30	55.34	0.255
	Control Group	20	162.55	52.70	
Sr. T.G BT	Test Group	20	261.08	198.39	0.934
	Control Group	20	256.77	116.42	
Sr. TG.AT	Test Group	20	223.91	81.76	0.74
	Control Group	20	214.97	87.61	
Sr. HDL BT	Test Group	20	51.11	9.31	0.413
	Control Group	20	53.65	10.08	
Sr. HDL AT	Test Group	20	51.52	8.00	0.705
	Control Group	20	52.63	10.18	
Sr. LDL BT	Test Group	20	144.74	29.39	0.821
	Control Group	20	142.64	29.09	
Sr. LDL AT	Test Group	20	137.51	34.75	0.011
	Control Group	20	106.92	37.76	

Table 7: Comparison of Objective parameters before and after thetreatment with in Test group.					
Objective parameters		**Mean**	**N**	**Std. Deviation**	**P value**
Sr. Chol (mg/dl)	BT	174.9500	20	48.63016	0.650
	AT	182.3000	20	55.33829	
Sr. TGL (mg/dl)	BT	261.0750	20	198.38891	0.378
	AT	223.9100	20	81.75849	
Sr. HDL (mg/dl)	BT	71.3050	20	89.13655	0.331
	AT	51.5200	20	7.99701	
Sr. LDL (mg/dl)	BT	144.7400	20	29.39453	0.391
	AT	137.5050	20	34.74641	

IX. DISCUSSION

The clinical study was conducted to evaluate the efficacy of Bādranjboya (Melissa officinalis) in Dyslipidaemia. This was an open labelled, randomized, Comparative, pre and post clinical study, with 40 patients (20 in test group and 20 in control group) belonging to 20-50 years of age, irrespective of gender. out of 47 patients 40 completed, 45 days protocol, 7 patients (3 in test and 4 in control) were dropped out. The test group was treated with Joshandae (Decoction) Bādranjboya (25 gm of dried leaves) empty stomach in the morning once a day orally, whereas control group was managed, with one tablet of Atorvastatin 10 mg twice a day orally for 45 days. Subjective parameter (joint pain) were assessed based on Visual Analogue Scale (VAS) on every 15th day of follow up and Objective parameters were carried out before and after treatment in each group. This study stretched from July 2019 to December 2020.

According to dietary distribution 37 (92.5%) patients had mixed diet habit and only 3 (7.5%) patients were vegetarian. Consuming more fatty diet is a factor of Dyslipidaemia. The distribution of dietary habit among patients, we observed that there is no significant difference between the two groups because p-value is 0.2310 It is suggested that more fatty diet causes lipoprotein disorders by Stephen J Mc Phee and Maxine A. Papadakis (2010).

Out of 40 patients 15 (37.5%) have Balghami Mizaj while 14 (35%) patients were of Damvi Mizaj, 9 (22.5%) patients were of Safravi Mizaj and 2 (0.5%) patients were of Saudavi Mizaj. It reveals an insignificant difference between test and control group with respect to mizaj of patients since p value is 0.5970. It is mentioned that Baroodate Jigar produces more Khilte Balgham, which provides nutrition to all organs. Ultimately temperament of organs becomes Balghami (Phlegmatic). The nature of disease is progressive, and asymptomatic. It may be diagnosed accidentally or during routine investigations. It also depends upon the awareness of individual. Palpitation and breathlessness was assessed on the severity of disease and extent of involvement were assessed by using (Arbitrarily Scale) graded as severe, moderate, mild and absent/normal and was coded as 3+, 2+, 1+ and 0 respectively. Chi-square test was employed for inter group comparison of categorical variables and for intra group analysis of categorical variable with more than two levels we applied McNemar- Bowker's test. It was evident that there is a no significant difference between the groups with respect to palpitation and breathlessness, however; there is a strong significant difference before and after the treatment in both test and control group because the severity of palpitation and breathlessness among patients in both the groups significantly improves to normality after the treatment. For the significance of pain in test and control group we applied paired t-test was applied for intra-group analysis. We observed that both the treatments are almost equally effective because there is a clear significant difference before and after the treatment within both test and control group as p value is <0.05. To analyse the difference between test and control group with respect pain we used students independent test and observed that both the treatments areinsignificantly equally effective.

Joints pain was assessed on the severity of disease and extent of involvement were assessed by using VAS (Visual Analogue Scale) consists of a line, often 10 cm long, which was graded as severe, moderate, mild and absent. The mean score of joints pain was calculated in both control and test group on 0th, 15th, 30th and 45th day as Comparison between test and control group at base line and after the treatment with respect to subjective parameters. The mean scores of both groups were compared statistically using Student's independent t-test for inter group. (p value is >0.346). Paired t-test was applied for intra-group analysis. It was found that the descriptive statistics of subjective parameter like pain for test and control group at base line and last follow up. We observed that both the treatments are almost equally effective because there is no significant difference between the two groups as p value is >0.05 at 45th day. Comparison of subjective parameters before and after the treatment within test group, In test group there is a significant difference before and after the treatment with respect to subjective parameters within the test group since (p value <0.001) at 45th day with respect to test day 0, and also significant difference (p value <0.001) at 45th day with respect to test day 15.

Comparison of subjective parameters before and after the treatment within control group, In control group there is a significant difference before and after the treatment with respect to subjective parameters within the control group since p value is <0.001 at 45th day with respect to control day 0, and also significant difference (p value <0.001) at

45th day with respect to control day 15.

Present result on palpitation, breathlessness and joints pain reveals that the both treatments are almost equally effective because there is no significant difference between the two groups as p value is >0.05 at 45th day on all subjective parameters. High level of lipoproteins develops cardiovascular disease symptoms and peripheral vascular symptoms.

The exact mechanism of action of Melissa officinalis is not known, however, in other studies, mentioned by Marongiu B, the essential oil of M. officinalis has these chemical constituents are i.e. flavonoids (luteolin, quercitrin, rhamnocitrin) monoterpenoid aldehyde, triterpenes (ursolic and oleanolic acids), polyphenolic compounds (rosmarinic acid, caffeic, and protocatechuic acid), monotherpenoid aldehides, sesquiterpenes, tannins and monoterpene glycosides and which play a key role in heartdisease prevention by their antioxidant activity.
A study on Melissa officinalis L. (lemon balm) leaf extract has shown to contain more than 5% hydroxycinnamic acid content is known to have anti-anxiety effects. A study has reported the significant immunomodulatory activity of ethanolic extract of Melissa officinalis presented a strong immunomodulatory potential. Serum Cholesterol was assessed before and after treatment in both test and control group. The Mean ± SD score of test group was (174.95 ± 48.63) on base line and (182.30 ± 55.34) on 45th day. In control group Mean ± SD score was (179.50 ±38.79) on baseline and (162.55 ± 52.70) on 45th day respectively (Table No. 11). We analysedintra group data comparison by Paired-t test for inter group comparison we applied student independent t-test. We observed that Serum Cholesterol level in both the groups at base line and found that they were comparable with a p-value of 0.745. However, we also observed that there was an insignificant difference between the two groups with respect to the effect on Cholesterol levels after the treatment as the p-valuewas >0.05.

In this study Bādranjboya has effect on most of the parameters which is evident from statistical analysis, since the p-value is <0.001* for almost all the parameters including palpitation, breathlessness and joint pain, however, there was an insignificant difference before and after the treatment with respect to some parameters like Cholesterol, Triglyceride and HDL in both test and control group except for LDL showed some improvement in control group. In case of safety parameters, we observed they remained within normal range before and after the treatment which indicates that both the treatments are safe to patients. However, haemoglobin level among patients in test group improved which is evident from the statistical analysis as the p value is <0.001*.

X. SUMMARY

Subjective and objective parameters were assessed and noted in Case Report Proforma.After completion of study, the result was analysed and observed that both the treatments are almost equally effective because there is no significant difference between the two groups as p value is >0.05. Overall, improvement was observed in test group, without any clinically and statistically significant side effects or toxicity. The compliance to the treatment was found good. These results conclude that the test drug is quite safe in the treatment of Dyslipidaemia.

The present study was an open labelled, randomized, Comparative, pre and post analysisconducted in RRIUM, Hospital, University of Kashmir, Srinagar to evaluate the efficacy of test drug Bādranjboya, (Melissa officinalis) in the management of Dyslipidaemia. Cases were selected on the basis of clinical diagnosis, inclusion and exclusion criteria in the research protocol. The protocol duration was 45 days. Cases were randomly assigned in two groups; test group comprising 20 patients, while control group consisting 20 patients. The efficacy of the both test and control drugs were assessed on the basis of clinical examination and laboratory investigations.

Findings of effectiveness of both drugs were recorded in CRF and the inference was made by appropriate statistical analysis. Summary of demographic data, effects oftreatment on different subjective and objective parameters are as follows.

A. Demographic Data

- Dietary Habit.

According to dietary distribution 37 (92.5%) patients had mixed diet habit and only 3 (7.5%) patients were vegetarian.

- Mizaj

15 (37.5%) Maximum patients were found to be having Balghami izaj14 (35%) patients were found to be having Damvi Mizaj, 9 (22.5%) patients were found to be having Safravi Mizaj 2 (5%) patients were found to be having Saudawi Mizaj with respectively.

B. Subjective Parameters

- **Effect on palpitation and breathlessness**

Palpitation was categorised in severity, moderate, mild and normal class using arbitrarily scale Chi-square test was employed for inter group comparison of categorical variables and for intra group analysis of categorical variable with more than two levels we appliedMcNemar-Bowker's test. It was evident that there is a no significant difference between the groups with respect to palpitation and breathlessness (p-value >0.05), however; there is a strong significant difference before and after the treatment in both test and control group (P-value<0.001*) because the severity of palpitation among patients in both the groups significantly improves to normality after the treatment.

➢ **Effect on joints pain**

The mean scores of both groups were compared statistically, it was found that both the groups were comparable at 0 day. However, there was a significant decline in average VAS value after the treatment (45th day) in both the groups because the p value is (<0.001*) in each group. Evidently both the treatments are equally effective in respectof effect on joints pain.

CONCLUSION

The study was a randomized, comparative, pre and post clinical in nature aimed to evaluate the efficacy of drug in the management of Dyslipidaemia. The scientifically chosen sample size 40 was divided in two groups; 20 patients were randomly allocated to test group and 20 patients were randomly allocated in control group. Test group was treated with Joshandae Bādranjboya (25 gm of dried leaves) empty stomach in the morning once a day orally, whereas control group was managed, with one tablet of Atorvastatin 10 mg twice a day orally for 45 days. All patients who qualified the inclusion criteria were included in the study. Treatment protocol was followed for 15 days in both groups, subjective and objective parameters were recorded in each followup i.e., 0, 15th, 30th and 45th day, The severity of disease and extent of involvement was assessed either by arbitrarily scale or by using VAS (Visual Analogue Scale).

The overall effect of the Bādranjboya was found quite encouraging in the treatment of Dyslipidaemia. Drastic improvement in subjective parameters like palpitation, breathlessness and joints pain was seen in patients placed in both test and control group as the same is evident from statistical analysis, however, some parameters like; Cholesterol, Triglyceride, HDL and LDL did not show significant improvement in either groups. In conclusion we observed that both the treatments are almost equally effective on parameters like palpitation, breathlessness, joint pain and equally not effective on Cholesterol, Triglyceride, HDL and LDL. However, for test group patients there was a significant improvement in haemoglobin level of patients since the p-value corresponding to haemoglobin level (before and after) is <0.001*. Interestingly, we observed that in test group, safety parameters remained under normal range after the administration of Bādranjboya which rules out any possible side effects or toxicity of the drug. The compliance to the treatment was found good. These results conclude that the test drug is quite safe in the treatment of Dyslipidaemia. However, long term study on larger sample size is required for furtherexploration of the effects of Bādranjboya, and also to determine their mechanism of action with modified methodology.

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