Research Article

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Theraputic potential of *Enicostoma littorale blume* (Mamajjaka) in Metabolic Syndrome

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Abstract:

Objective: The main objective of the present work to evaluate the therapeutic potential of standardized aqueous extract of *Enicostoma littorale blume (Mamajjaka)* in Metabolic Syndrome (MS) patients**.**

Design: Single blind clinical trial

Methodology: In this present study, total 50 (N=50) previously diagnosed MS patients were randomly selected and divided into two groups having 25 patients in each group. In group I (n=25) patient have advised to take starch capsule 500mg TID as a placebo and in Group II (n=25) standardized aqueous extract of *E. littorale blume (Mamajjaka)* 500mg TID has been given for 3 month with follow up of 1 month. During the entire course of therapy patients were advised to continue their ongoing conventional treatment along with trial drug.

Result: Statistical analysis showed significant improvement in dyslipidemic state and hyperglycemic state of MS patient as compared to placebo group**.**

Conclusion: The aqueous extract of *E. littorale blume (Mamajjaka)* exhibit excellent hypolipidemic and hypoglycemic potential in MS patients

Keywords: *Enicostoma littorale blume,* Mamajjaka, Metabolic Syndrome(MS), dyslipidemia.

INTRODUCTION:

Metabolic Syndrome is the cluster of diseases which are mainly due to the re-arrangement of the metabolic process of the body. It was first described by Reaven in 1888, but the groups of diseases that are associated with Metabolic Syndrome are familiar from the very beginning. Metabolic syndrome is recognized as one of the major public health challenges worldwide and especially in Indian sub-continent[1]. It is most common in adult population throughout the world[2]. Metabolic Syndrome is a set of risk factors that includes abdominal obesity, Insulin resistance, Hypertension; Dyslipidemia (raised triglycerides and low HDL-cholesterol). Metabolic syndrome in its path physiological perspective mainly deals with the regulation of insulin resistance, atherogenic dyslipidemia, hypertension, impaired glycemia, pro-inflammatory state or endothelial dysfunction, pro-thrombotic state, abnormal fat metabolism, fatty liver, abnormal ovarian androgen secretion. It is estimated that approximately 25% of the world's population has MS and it will increased up to 38% by the year 2023[3]. Individuals, who were physically inactive, obese and genetically predisposed have greater risk of insulin resistance. Insulin resistance and abdominal obesity vice-versa affects each other and it may lead to poorly understood complex set biological mechanism at cellular level, which play a significant role in the genesis of MS and other associated risk factors[4]. The major diagnostic features of MS include central obesity, hypertriglyceridemia, decrease high-density lipoprotein (HDL), hyperglycaemia and hypertension[5].

Globally three definitions of the metabolic syndrome are currently most populer : the World Health Organization (WHO) definition; the European Group for the study of Insulin Resistance (EGIR) definition; and the National Cholesterol Education Programme Expert Panel Adult Treatment Panel III (NCEP: ATP III) definition[5].

Due to remarkable risk profile of modern synthetic anti-diabetic, anti-hypertensive, anti-obesity and hypolipidemic agents there is an urgent need to develop eco-friendly, bio-friendly plant based products to replace synthetic chemicals particularly. Ayurveda has listed a number of medicinal plants with their anti-diabetic, anti-obesity and hypolipidemic properties. The *E. littorale blume (Mamajjaka)* is one of them. It

possess hypoglycemic and hypolipidemic potentials acting through different pathways[6]. It is also reported that this plant is useful in diabetes mellitus[7]. It has strong antioxidant/free radical scavenging properties which could prevent the occurrence of heart related diseases[8] . Keeping in view the above concept, the present research work was carried out at OPD and IPD of Kayachikitsa, Sir Sunderlal Hospital, I.M.S., B.H.U., Varanasi.

Objectives:

To evaluate the theraputic potential of standardized aqueous extract of *E. littorale blume (Mamajjaka)* in Metabolic Syndrome (MS) patients.

Study Design: Single blind clinical trial

Methods:

A total 50 cases of Metabolic Syndrome were randomly selected from OPD and IPD of Kayacikitsa, S. S. Hospital, IMS, B.H.U, Varanasi after thorough history taking, clinical and laboratory examination. The study was undertaken in duration of September 2012 to December 2014. Prior to the study, the approval of the institutional ethical committee was obtained. Patients were randomly divided into two groups, 25 patients in each group with care of inclusion and exclusion criteria has been taken. All the registered patients were already diagnosed as MS and taking conventional modern medicine for their treatment but they were still in dyslipidemic and hyperglycemic state, So they were came to us for add on ayurvedic treatment. Most of the patients were come to our hospital directly, while some of them were referred cases from other medical centers or from local doctors. Before registration of case all the patients were subjected for repeat diagnostic screening for MS.

Inclusion criteria:

All patients fulfilling 2001 NCEP/ATP III[5] the criteria to define metabolic syndrome (presence of any three of the following five traits) for M.S were taken.

- Age between: 20-60 years of either sex.
- Waist ≥ 102cm (men), > 88cm (women)
- Hypertension > 130/85 or taking T/t
- Triglycerides ≥ 150 mg/dl or taking T/t
- HDL-cholesterol < 40 mg/dl
- Fasting plasma glucose ≥ 100mg/dl
- Patients having clinical signs and symptoms of Sthaulya.
- Patients willing for trial.

Exclusion criteria:

- Age <20yrs. and >70yrs.
- Type I and Type II Diabetes Mellitus (NIDDM) with major complications.
- Obese and Hypertensive patients with other major complications.
- Drug or chemical induced diabetes mellitus e.g. Glucocorticoids etc.
- Certain genetic syndromes e.g. Down's syndrome, Klinefelter's syndrome, Turner's syndrome etc.
- Patients suffering from other severe systemic diseases.

Termination criteria :

- Sudden deterioration in patient's health status during the period of study.
- Non compliance of the patient.

Availability of trial drug:

Standardized aqueous extract of trial drug ***Mamajjaka (Enicostoma littorale blume)*** was purchased from Konark Herbal Pvt. Ltd., Gujrat (GMP certified well reputed extract provider company) after permission of DRC and Head of the department. After that capsuling of 500mg strength was done and packed in the bottle.

Grouping of Patients:

- **Group 1 (n=25)** Placebo group patients were advised to take starch capsule 500 mg three times a day orally after meal along with ongoing conventional treatment.
- **Group 2 (n=25)** patients were advised to take capsule of standardized aqueous extract ***Mamajjaka (Enicostoma littorale blume)*** 500mg three times a day orally after meal along with ongoing conventional treatment.

Parameter of assessment:

1) Blood Sugar Fasting (FBS.)
2) Blood Sugar Postprandial (PPBS)
3) Serum Cholesterol
4) Serum Triglycerides (TG)
5) Serum High density lipoprotein (HDL)
6) Serum High density lipoprotein (LDL)
7) Serum Vary low density lipoprotein (VLDL)

Statistical Analysis:

The data obtained was processed on a computer with the help of "SPSS: 16" software package of statistical analysis. Standard statistical methods were used to determine the mean, standard deviation (SD) and the range. Paired t-test was used to compare the results of various biochemical parameters among the patients in the four groups. All value quoted as the mean ± SD and a p-value of < 0.05 was considered to be statistically

significant and p-value of <0.01 or p < 0.001 was considered to be statistically highly significant.

OBSERVATION AND RESULTS:

Table 1. Mean change in FBS in patients of Metabolic Syndrome[N=50]:

Groups	BT	FU1	FU2	FU3	Paired 't' test BTvs FU3 Mean±SD	t value	p value
Group I (n=25) (Placebo)	112.64 ±22.44	108.11 ±17.77	104.84 ±22.59	105.24±22.11	7.40 ±9.82	3.77	0.001
Group II (n=25) (AME)#	123.04 ±31.67	104.68±21.98	103.60 ±19.18	98.36 ±16.21	24.68 ±25.97	4.75	<0.001

Table 2. Mean change in PPBS in patients of Metabolic Syndrome[N=50]:

Groups	BT	FU1	FU2	FU3	Paired 't' test BTvs FU3 Mean±SD	t value	p value
Group I (n=25) (Placebo)	165.16±48.55	162.47±42.09	157.92±44.52	156.48±38.42	8.68±22.79	1.90	0.069
Group II (n=25) (AME)#	158.80±44.13	144.04±33.02	138.08±32.41	140.80±29.49	18.00±33.00	2.73	0.012

Table 3. Mean change in S.Cholesterol in patients of Metabolic Syndrome[N=50]:

Groups	BT	FU1	FU2	FU3	Paired 't' test BTvs FU3 Mean±SD	t value	p value
Group I (n=25) (Placebo)	210.88±72.93	198.32±65.48	195.88±66.06	196.84±65.65	14.04±25.11	2.80	0.01
Group II (n=25) (AME)#	226.96±81.40	183.32±49.86	173.52±34.37	163.16±27.63	63.80±73.63	4.33	<0.001

Table 4. Mean change in S. Triglycerides in patients of Metabolic Syndrome[N=50]:

Groups	BT	FU1	FU2	FU3	Paired 't' test BTvs FU3 Mean±SD	t value	p value
Group I (n=25) (Placebo)	194.96±64.12	179.32±47.43	172.96±47.56	177.40±44.25	17.56±46.82	1.88	0.073
Group II (n=25) (AME)#	202.92±66.92	169.28±44.54	151.40±33.23	140.52±27.23	62.40±70.22	4.44	<0.001

Table 5. Mean change in S.HDL in patients of Metabolic Syndrome[N=50]:

Groups	BT	FU1	FU2	FU3	Paired 't' test BTvs FU3 Mean±SD	t value	p value
Group I (n=25) (Placebo)	42.68±10.31	44.12±8.23	44.32±8.29	44.08±8.13	-1.40±4.99	-1.40	0.174
Group II (n=25) (AME)#	38.04±7.89	41.40±5.65	42.20±6.06	43.12±5.36	-5.08±5.72	-4.45	<0.001

Table 6. Mean change in S.LDL in patients of Metabolic Syndrome[N=50]:

Groups	BT	FU1	FU2	FU3	Paired 't' test BTvs FU3 Mean±SD	t value	p value
Group I (n=25) (Plcebo)	121.23 ±63.69	112.32±57.23	110.56 ±55.89	116.00 ±59.22	5.23 ±27.32	0.96	0.35
Group II (n=25) (AME)#	111.36 ±29.98	105.84±19.99	96.96 ±22.32	95.00 ±19.98	16.36 ±20.48	3.99	0.001

Table 7. Mean change in S.VLDL in patients of Metabolic Syndrome[N=50]:

Groups	BT	FU1	FU2	FU3	Paired 't' test BTvs FU3 Mean±SD	t value	p value
Group I (n=25) (Plcebo)	44.12 ±20.64	48.32±15.48	45.12 ±13.61	44.16 ±13.71	-0.04 ±10.47	-0.02	0.98
Group II (n=25) (AME)#	41.20 ±13.74	35.04 ±9.17	34.44 ±9.33	33.96 ±10.59	7.24 ±15.43	2.35	0.03

[#AME= Aqueous Mamajjaka Extract, B.T=Before treatment, FU- Follow up, S.D=Standard deviation]

DISCUSSION:

The FBS level significantly decrease in all group ($p<0.001$) but maximum decrease found in Group-II (BT- FU3) mean ± S.D. was 24.68±25.97 ($p<0.001$) than Group-1 (BT- FU3) mean ± S.D 7.40±9.82 ($p=0.001$) PPBS level significantly decrease in Group- II (BT- FU3) mean ± S.D. was 18.00±33.00 ($p=0.012$) as compared to Group- I (BT- FU3) mean ± S.D 8.68±22.79 ($p=0.069$). Serum cholestrol level significantly decrease in Group-II (BT- FU3) mean ± S.D. was 63.80±73.63 ($p<0.001$). Least improvement found in Group- 1 (BT- FU3) mean ± S.D 14.04±25.11 ($p=0.01$) Serum triglyceride level significantly decrease in Group-II (BT- FU3) mean ± S.D. was 62.40±70.22 ($p<0.001$) least improvement found in Group –I ($p=0.073$). Serum HDL level significantly increase in Group-II during study (BT- FU3) mean ± S.D. was -5.08±5.72 ($p<0.001$) while in Group-I there were very nominal change during entire study period. ($p=0.174$) Serum LDL level significant decrease detected in Group-II (BT- FU3) mean ± S.D. was 16.36±20.48 ($p=0.001$) followed by Group-I (BT- FU3) mean ± S.D was (5.23±27.32, $p=0.35$). Serum VLDL level significant decrease again detected in Group- II (BT- FU3) mean ± S.D. was 7.24±15.43 ($p=0.03$). While in placebo group there were not any significant change observed ($p=0.98$). In short we can say that Mamajjaka (*Enicostoma littorale blume*) exhibit excellent hypoglycemic and hypolipidemic action which are major risk factors in Metabolic Syndrome patients. Mamajjaka is an ancient ayurvedic herb indiacated for diabetes and liver disorders. The main active constituent in this plant is Mamajjaka plant is “Swartiamarin”. Which is very good Antioxident[9][10],Antihyperlipidemic[6][11][12], Hypoglycemic[7][8], Antihyperinsulinemic[13][14] and Hepatoprotective properties[15]. All above action are helpful to antagonize the pathology of Metabolic Syndrome.

Conclusion:

In this study significant decline in FBS, PPBS, Cholestrol, TG, LDL, VLDL and Significant increase in S.HDL heve been observed. ($p\leq0.001$). So we can conclude that Standardized aqueous extract ***Mamajjaka (Enicostoma littorale blume) have*** shown potent Hypoglycemic and Antihyperlipidemic action as compare to placebo group.

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