Int. J. Ayur. Pharma Research, 2015;3(2):80-85 **ISSN: 2322 - 0910**

International Journal of Ayurveda and Pharma Research

Research Article

EVALUATION OF COMPARATIVE EFFICACY OF *NEELKANTHI* (AJUGA BRACTEOSA), *TEJAPATRA* (CINNAMOMUM TAMALA) AND *METHIKA BEEJA* (TRIGONELLA FOENUM GRAECUM) *CHURNA* IN THE MANAGEMENT OF DIABETES MELLITUS

Vijay Chaudhary[1], Sharad Johri[2], Ashwani Kumar Rana[3*]

[1]Reader, Dept. of Kayachikitsa, R.G. Govt. P.G. Ayu. College, Paprola, H.P., India.

[2]Dept. of Kayachikitsa, State Ayu. College, Lucknow, U.P., India.

[*3]Lecturer, Dept. of Kaumarbhritya, G.A.C., Patiala, Punjab, India.

Received on: 29/01/2015 Revised on: 11/02/2015 Accepted on: 20/02/2015

ABSTRACT

Introduction: Diabetes mellitus is a disease since antiquity. It is emerging as a pandemic in the society. Though a lot of potent antidiabetic drugs are available today but none of them is free from untoward effects. A number of *Ayurvedic* herbal drugs are effective in the management of diabetes mellitus. But most of these drugs are required to be taken in bulk invariably for long span hence some time their poor palatability becomes a big problem. Moreover which herbal is more potent and in which particular situation it is more suitable also needs to be evaluated.

Objective: This study was conducted to clinically evaluate comparative efficacy of *Neelkanthi Churna, Tejapatra* and *Methika Beeja Churna* in the management of diabetes mellitus.

Materials and Methods: The study was conducted as a part of post graduate thesis research work. Total 45 patients of diabetes mellitus were registered in the present clinical study and they were administered trial drugs for the duration of 45 days. Registered patients were randomly divided into two groups. In group-I patients were managed with *Tejapatra* and *Methika Beeja Churna*. Group-II patients were managed with *Neelkanthi Churna.*

Observations and conclusion: Patients were thoroughly assessed on various parameters during complete trial period. Though both *Churna* of *Neelkanthi* and *Churna* of *Tejapatra* and *Methika Beeja* were found significantly effective in the management of *Madhumeha* but *Churna* of *Neelkanthi* showed definitely better effect on various subjective, objective and biochemical parameters. No untoward effect was noticed during treatment and follow up period.

KEY WORDS: *Madhumeha,* Diabetes mellitus*, Neelkanthi, Tejpatra, Methika,* herbal drugs*.*

INTRODUCTION

Diabetes mellitus is a disease since antiquity. Today the whole world is facing a pandemic of diabetes mellitus. Globally and nationally diabetes mellitus with its complications has become one of the most important challenging health problem. Changing life style, lack of exercise, fast foods, improper diet and sedentary life are showing upward trend in India. This has lead to the emergence of diabetes mellitus in this region. A number of Ayurvedic herbal drugs are effective in the management of *Madhumeha*. *Neelkanthi*, *Tejapatra* and *Methika Beeja* are also among them. But as the anti diabetic drugs are required to be taken in bulk invariably for long span hence some time their poor palatability becomes a big problem. Moreover which herbal is more potent and in which particular situation it is more suitable also needs to be evaluated. In the present study, comparative efficacy of *Neelkanthi Churna*, *Tejapatra* and *Methika Beeja Churna* has been clinically assessed in type-II diabetes mellitus patients.

Objectives of the Research work

To clinically evaluate comparative efficacy of *Neelkanthi Churna* (*Ajuga bracteosa* wall. ex benth), *Tejapatra* (*Cinnamomum tamala*) and *Methika Beeja Churna* (*Trigonella foenum* graecum) in the management of diabetes mellitus.

Location/ Setting: The study was conducted as a part of post graduate thesis research work in P.G. department of Kayachikitsa (Medicine) of Rajiv Gandhi Govt. Post Graduate *Ayurvedic* College & Hospital Paprola, Himachal Pradesh in the year 2011.

MATERIALS AND METHODS

The present study was open, single blind and double group in nature. The study was conducted on 45 patients of diabetes mellitus selected from OPD and IPD of associated hospital of Rajiv Gandhi Govt. Post Graduate *Ayurvedic* College, Paprola (H.P.). Patients of type-II diabetes mellitus in the age group of 35-80 years were registered irrespective of caste, sex, race and religion after obtaining their written informed consent. 5 patients did not turn up for follow up. They were considered dropped out from the study. Remaining 40 patients completed the trial.

Criteria for Diagnosis

1. **Subjective Criteria:** Classical signs and symptoms of *Madhumeha* mentioned in *Ayurvedic* texts as well as in modern medicines.
2. **Objective Criteria:** Fasting blood glucose > 126 mg/dl.

Inclusion Criteria

1. Age between 35-80 years.
2. Patients with FBS > 126 mg/dl.
3. Only uncomplicated cases of type-II diabetes mellitus.

Exclusion Criteria

1. Patients presenting with complications like severe renal disease, retinopathy, ischaemic heart disease, severe hypertension etc.
2. type-I diabetes mellitus.
3. Patients underwent pancreatic or liver surgery.
4. Patients having associated major medical diseases like cancer and concurrent infection like tuberculosis etc.

Method of Study: Total 45 patients of type-II diabetes mellitus were selected for the present clinical study, they were randomly divided into two groups and treatment was given as follows:

i. **Group I:** Total 23 patients were registered in trial group I and out of them 3 patients discontinued the treatment and only 20 patients completed the study, the selected patients were given the trial drugs i.e. *Tejpatra* and *Methika Beeja Churna* in equal quantity in the dose of 10 gms, twice a day with plain water before food.

ii. **Group II:** Total 22 patients were registered in trial group II and out of them 2 patients discontinued the treatment and only 20 patients completed the study, the selected patients were given *Neelkanthi Churna* in a dose of 2 gms twice a day with plain water before food.

Preparation of trial drugs

Trial drugs were prepared in state *Ayurvedic* pharmacy Paprola, which is G.M.P. certified. *Neelkanthi* (*Ajuga bracteosa* wall. ex benth) whole plant was grinded to prepare fine powder. *Tejapatra* (*Cinnamomum tamala*) leaves and *Methika* (*Trigonella foenum* graecum) seeds were also grinded to prepare fine powder.

Investigations: Following investigations were carried out to rule out any other concomitant disease, secondary hypertension and to see any untoward effect of the trial drugs both before and after the therapy.

Blood: Fasting blood sugar and urine- routine and microscopic examination were done at every15 days till the completion of trial. Other investigations which were carried out both before and after the therapy are as under:

Blood: Hb%, TLC, DLC, ESR, Blood Urea, S. Creatinine, Lipid profile (LDL, VLDL, HDL, S. Triglycerides, S. Cholesterol), S.G.O.T., S.G.P.T.

Duration of Trial: 45 days.

Data Collection and Statistical Analysis: Data generated from clinical study was collected and analyzed statistically. The improvement in the status of patient was assessed on the grades of various variables compared between pre-trial and post-trial values in terms of percentage (based on mathematical mean and its difference) and the student 't' tests was applied wherever it was felt necessary by using degree of freedom value. The results were interpreted at the level of $p<0.001$ as highly significant, $p<0.01$ as moderately significant, $p<0.05$ as significant and $p>0.05$ as insignificant.

Instructions to the Patients: Patients of both the groups were given similar advice regarding diet and exercise. All the patients were advised to take plenty of green leafy vegetables and to avoid high glycemic index food and fats. They were further advised to take light exercises daily and to avoid strenuous physical exercise.

Criteria for Assessment: Registered patients were thoroughly assessed for any improvement in

the subjective and objective criteria after every 15 days till the completion of trial of 45 days. Haematological, biochemical and urine examination were done both before and after the therapy. Various signs and symptoms and urine sugar were accorded grades according to the severity as under:

Table 1: Grading of symptoms

Symptoms	Grade
Absent	0
Mild	1
Moderate	2
Severe	3

Table 2: Grading of Urine Sugar

Urine Sugar	Grade
Nil	0
Trace	1
+	2
++	3
+++	4
++++	5

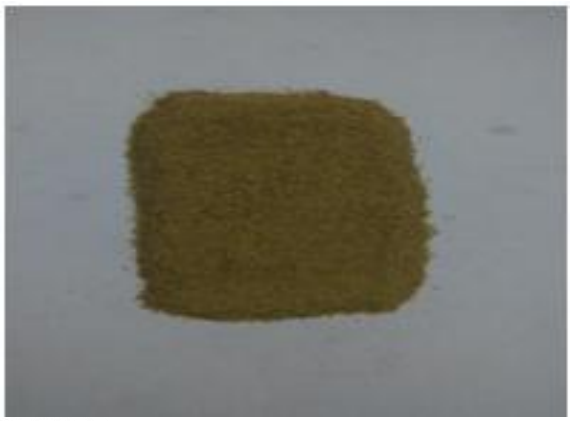
Observations: Statistically highly significant (p<0.001) reduction in fasting blood sugar was observed in both groups (Group-I 35.75%, group-II 40.99%). But intergroup difference was insignificant statistically (p>0.05). (Table 3)

Statistically moderately significant (p<0.01) reduction in urine sugar was observed in group-I (71%). In group-II urine sugar reduction was 80%, which was also statistically highly significant (p<0.001). But intergroup difference was insignificant statistically (p>0.05). (Table 4)

Statistically highly significant reduction in polyuria, polydipsia, polyphagia, fatigue, numbness, burning sensation of hands and feet, calf tenderness, dryness of mouth, joint pains and vulval pruritus/balanitis in both groups. However intergroup difference was insignificant statistically (p>0.05) for all features except polyuria. (Table 5).

Haemoglobin, TLC, DLC, ESR, blood urea and serum creatinine, SGOT, SGPT were within normal limits before starting of therapy and remained so after completion of trial in both the groups and statistically insignificant effect was observed in both the groups after the therapies. In Group-I patients serum lipid profile status was statistically significantly improved (p<0.001) whereas in no change was observed in Group-II (p>0.05). (Table 6)

Trial Drugs Pictures



Tejapatra + Methika Beeja Churna

Neelkanthi Churna

Table 3: Comparative effect of therapy on fasting blood sugar

Variable (Mean score)	Trial Group I						Trial Group II						Comparison	
	Mean score		% change	+ SE	t	p	Mean score		% Change	+ SE	t	p	I Vs II 't'	P
	BT	AT					BT	AT						
Fasting Blood Sugar	176.5	113.4	35.75	5.42	11.86	<0.001	173.3	102.25	40.99	<0.001	12.8	<0.001	0.85	>0.05

Table 4: Comparative effect of therapy on Urine Sugar

Variable (Mean score)	Trial Group I						Trial Group II						Comparison	
	Mean score		% change	± SE	T	p	Mean score		% change	± SE	T	p	I Vs II 't'	p
	BT	AT					BT	AT						
Urine Sugar	2	0.58	71	0.34	4.14	<0.01	1.84	0.30	83	0.26	5.88	<0.001	0.38	>0.05

Table 5: Comparative effect of therapy on symptoms

Signs/ Symptoms	Trial Group I						Trial Group II						Comparison	
	Mean score		% change	+ SE	t	P	Mean score		% change	+ SE	t	p	I Vs II 't'	P
	BT	AT					BT	AT						
Polyuria	0.91	0.17	81	0.07	10.71	<0.001	1.63	0.05	96	0.15	10.26	<0.001	3.6	<0.01
Polydipsia	1.36	0.36	73	00	00	<0.05	1.50	0.20	86	0.15	8.66	<0.001	2	>0.05
Polyphagia	1.45	0.36	75	0.09	12.11	<0.001	1.40	0.20	85	0.13	9.23	<0.001	0.27	>0.05
Fatigue	1.40	0.30	78	0.09	12.22	<0.001	1.40	0.20	85	0.13	9.23	<0.001	0.62	>0.05
Numbness	1.30	0.20	84	0.09	12.22	<0.001	1.54	0.18	88	0.07	19.42	<0.001	2.03	>0.05
burning sensation in hands and feet	1.72	0.45	73	0.13	9.76	<0.001	1.70	0.30	82	0.08	17.5	<0.001	0.86	>0.05
calf tenderness	1.44	0.44	69	00	00	<0.05	1.44	0.22	84	0.15	8.00	<0.001	1.54	>0.05
dryness of mouth	1.75	0.50	86	0.29	4.31	<0.01	1.54	0.18	88	0.15	8.66	<0.001	0.36	>0.05
joint pains	1.45	0.36	75	0.02	54.50	<0.001	1.45	0.18	87	0.14	8.57	<0.001	1.28	>0.05
Vulval pruritus/Balanitis	1.55	0.33	78	0.14	8.57	<0.001	1.57	0.28	82	0.19	6.31	<0.001	0.27	>0.05

Table 6: Comparative effect of therapy on lab parameters

Variable	Group-I							Group – II						
	Mean Score		% Change	SD	SE +	t	P	Mean Score		% Change	SD	SE ±	t	P
	BT	AT						BT	AT					
Haemoglobin	10.63	10.83	02.06	0.93	0.16	1.38	>0.05	10.80	10.91	01.02	0.44	0.065	1.69	>0.05
TLC	7414.2	7354.2	00.88	288.7	48.77	1.23	>0.05	6956.8	6920	00.53	1163	173.4	0.97	>0.05
ESR	16.91	16.02	05.26	3.49	0.59	1.49	>0.05	17.47	17.15	01.83	2.74	0.41	0.76	>0.05
Polymorphs	64.88	64.11	01.19	3.26	0.55	1.40	>0.05	62.37	63.64	02.03	6.31	0.94	0.85	>0.05
Lymphocytes	31.54	32.23	02.19	2.28	0.38	1.79	>0.05	33.84	30.00	11.34	5.38	0.80	0.51	>0.05
Monocytes	00.83	01.14	37.34	0.93	0.16	1.94	>0.05	01.16	01.27	09.48	0.96	0.14	0.77	>0.05
Eosinophils	02.74	02.28	00.17	1.24	0.21	1.09	>0.05	02.82	02.73	03.14	1.08	0.16	0.56	>0.05
B. Urea	32.28	31.80	01.50	3.10	0.52	00.92	>0.05	28.07	27.51	1.99	2.03	0.302	1.98	>0.05
S.Creatinine	00.94	00.92	02.12	0.12	0.02	01.25	>0.05	00.97	00.93	4.12	0.14	0.021	1.90	>0.05
SGOT	26.17	25.83	01.31	1.75	0.29	01.25	>0.05	24.80	24.47	1.33	1.79	0.27	1.41	>0.05
SGPT	27.83	27.28	01.95	2.56	0.43	01.93	>0.05	23.20	23.29	0.38	2.15	0.32	1.125	>0.05
S. Cholesterol	223.75	192.85	14.25	8.30	1.85	16.97	<0.001	214.38	214	0.001	2.76	0.41	0.88	>0.05
S. Triglyceride	152.8	128.4	15.96	4.18	0.93	26.23	<0.001	147.48	147	0.003	2.34	0.35	1.26	>0.05
HDL	45.4	52.1	14.75	1.75	0.39	17.17	<0.001	37.13	37.46	0.88	1.53	0.23	1.35	>0.05
LDL	138.25	118.75	14.10	7.55	1.68	11.60	<0.001	139.22	139	0.001	1.06	0.16	1.25	>0.05
VLDL	48.90	40.60	16.97	3.69	0.82	14.51	<0.001	37.80	37.47	0.87	1.43	0.21	1.57	>0.05

DISCUSSION

It has been established that *Tejpatra Churna* used in crude form contains more fibre which reduce glucose absorption from gut by inhibiting galactocidase and glucocidase. This drug can also be assumed to be acting at the level of pancreatic β-cells and thus increasing the insulin release. This can be explained on the basis that *Tejpatra* contain many aromatic oils and is widely used in spices. Now it is proved that all the spices help in activating the secretion of various digestive enzymes and hormones which helps in proper digestion and metabolism[1]. So it appears that *Tejpatra* may also stimulate directly or indirectly the β-cells of pancreas for proper insulin secretion and have hypoglycaemic effects[2]. Fenu greek seeds are used in crude form, the seeds contain more fibre which helps in reducing glucose absorption from gut, leading to reduced glucose load in blood. Fenu greek seeds contain the unique major free amino acid 4 - hydroxy isoleucine (4–OH – 11e) which has been characterized as one of the active ingredients in fenu greek for blood glucose control. Another mechanism mentioned about the trial drug is that, it may be acting against the formation of islet amyloid polypeptide (IAPP). It had been discovered that IAPP to be occurring in human insulinomas and in pancreatic islets with type-II diabetes mellitus, which have shown to inhibit insulin secretion and have hypoglycaemic effects [3,4]. *Neelkanthi Churna* is *Tikta* in *taste,* having *Sheeta Veerya* and *Katu Vipaka*, no anti-diabetic action of *Neelkanthi Churna* has been mentioned in Ayurvedic texts, but by virtue of its properties it acts as *Madhumehahara Aushada*. This is a folklore medicine wildly used in this area for the treatment of *Madhumeha*. The leaves contain more fibre

which helps in reducing glucose absorption from gut, leading to reduced glucose load in blood. This drug had been researched and proved to have hypoglycaemic effect[5].

CONCLUSIONS

On the basis of results obtained, it is clear that all three trial herbal drugs i.e. *Neelkanthi* (*Ajuga bracteosa* wall. ex benth)*, Tejapatra* (*Cinnamomum tamala*) and *Methika Beeja* (*Trigonella foenum* graecum) possess statistically significant hypoglycaemic activity. However *Neelkanthi Churna* showed definitely better efficacy over *Tejpatra* and *Methika Beeja Churna* in reducing fasting blood sugar, urine sugar and various subjective features of diabetes mellitus with no observed side effects. However *Tejapatra* and *Methika Beeja* may prove more useful in managing the type II diabetes mellitus patients having concomitant dyslipidemia as these drugs also possess significant hypolipidemic activities[6,7]. More studies are required for thorough assessment of antidiabetic potential of trial drug.

ACKNOWLEDGEMENT

The authors are thankful to all the patients who willingly participated in this study. We are also thankful to the management of Rajiv Gandhi Govt. Post Graduate *Ayurvedic* College & Hospital Paprola, H.P. and Govt. of Himachal Pradesh India for providing necessary assistance for completion of this research project.

REFERENCES

1. J.Rema, N.K.Leela, B.Krishnamoorthy and P.A.Mathew. Chemical composition of *Cinnamomum tamala* essential oil-a review. *Journal of Medicinal and Aromatic Plant Sciences* 27(2005) 515-519.
2. Sharma SR, Dwivedi SK, Swarup D. 1996. Hypoglycaemic and hypolipidemic effects of *Cinnamomum tamala* Nees. Leaves. *Indian Journal Experimental Biology* 34: 372-374.
3. Ullah Khan, F.,A. Ullah, S. Rehman, S. Naz and N. Naureen Rana, 2011. Fenugreek effect on muscle growth of broiler chicks. Res. Opin, Anim. Vet. Sci., 1: 1-3
4. Duke, J.A. and E.S. Ayensu, 1985. Medicinal Plants of China. Vol.1, Reference Publications, Algonac, MI., U.S.A., ISBN:9780917256264, Pages:705
5. Singh, Nikita et. al. (2003): A comparative clinical study of Neelkanthi with an Ayurvedic drug combination in the management of *Madhumeha* (diabetes mellitus.)
6. Bordia A., Verma S.K., Srivasta K.C. Effect of *Ginger* (Zingiber officinale Rosc.) and *Fenugreek* (Trigonella foenum graecum L.) on blood lipids, blood sugar and platelet aggregation in patients with coronary artery disease, 1997.
7. Xue, W.L., X.S., Li, J.Zhang, Y.H.Liu, Z.L. Wang and R.J.Zhang, 2007. Effect of Trigonella foenum-graecum (fenufreek) extract on blood glucose, blood lipid and hemorheological properties in streptozotocin- induced diabetic rats. Asia Pac. J. Cin. Nutr. 16:422-426.
8. *Charaka Samhita* (1991): Commentary by Brahmananda Tripathi, reprint edition, Vol. 1, 2, Chaukhambha Surbharti Prakashana, Varanasi.
9. *Sushruta Samhita* (1997): Commentary by Kaviraja Ambika Dutta Shastri, 11th edition, vol. 1 and 2 Chaukhambha Sanskrit Sansthan, Varanasi.
10. *Ashtanga Hridaya* (1990): commentary by, Sh. Lal Chandra Vaidya. Ist reprint, Moti Lal Banarasi Dass Publishers, Delhi.
11. *Ashtanga Samgraha* by *Vaghbhatta* : Hindi commentary by Kaviraja 'Atrideva Gupta, Volume 1 and 2, reprint 2002 Krishnadas Academy, Varanasi; Indu commentary by Dr. D.V. Pandit Rao and Vaidyanath Ayodhya Pandey.
12. *Bhava Prakasha* of Shri Bhava Mishra (8th edition 2003 Part-II) edited with Vidyotini Hindi Commentary by Bhishagaratna Pt. Shri. Brahma Shankara Mishra, Chaukhambha Sanskrit Sansthana, Varanasi.
13. Kirtikar, K.R. amd Basu, B.D. (1975): Indian Medicinal Plants, 2nd Edition, reprint Vol. III preiodical experts Delhi.
14. Madhava Nidanam (1990): Commentary by Shri Sudarshana Shastri, 19th edition, Chaukhambha Sanskrit Sansthana, Publishers and Dis tributors Varanasi.
15. Sandhir V. et. al. (2001): A clinical study of indigenous herbal drugs on *Madhumeha* with special reference to diabetes mellitus.
16. *Yogratnakara* (1973): Commentary by Shastri Lakshmipati, 2nd edition Chaukhambha Sanskrit Series, Varanasi.
17. Best and Taylors (1991): Physiologic basis of medical practice; edited by West, John B. 12th Edn., Williams and Wilkins, Baltimore, USA.

18. API (2004): Text Book of Medicine, Sainani, Gurmukh S. 7th Edition, Association of Physicians of India, Mumbai
19. Davidson's (2005) : Principles and Practice of Medicine, edited by, Christopher Haslett, Edwin R. Chilvers, John A.A. Hunter Nicholas A. Boon; Churchil Livingstone.
20. Harshmohan (2000): Textbook of Pathology, 4th Edition, Jaypee Brothers, New Delhi.
21. Harrison's (2005): Principals of Internal Medicine, 16th edition, international edition, Vol. 2 McGraw Hill, Medical Publishing Division.

Cite this article as:
Vijay Chaudhary, Sharad Johri, Ashwani Kumar Rana. Evaluation of Comparative Efficacy of Neelkanthi (Ajuga Bracteosa), Tejapatra (Cinnamomum Tamala) and Methika Beeja (Trigonella Foenum Graecum) Churna in the Management of Diabetes Mellitus. Int. J. Ayur. Pharma Research. 2015;3(2):80-85.
Source of support: Nil, Conflict of interest: None Declared

***Address for correspondence**
Dr. Ashwani Kumar Rana
Lecturer
Dept. of Kaumarbhritya
Govt. Ayurvedic College
Patiala, Punjab, India.
Email: drashwanirana@gmail.com
Mob: +919914591329