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Research Article

A COMPARATIVE CLINICAL EVALUATION OF ACACIA CATECHU (LINN. F.) WILLD. & AZADIRACHTA INDICA (A. JUSS.) W.S.R. TO DIABETES MELLITUS

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ABSTRACT

Objectiv: Comparison of effectiveness of drug Khadira twak churna in Group A and Nimba twak churna in Group B given same dose on patients of Diabetes mellitus.

Method: Patients between 30-70 yrs. of age with clinical signs and symptoms of Diabetes mellitus from OPD and IPD of Govt. Hospital were selected for the present work; irrespective of their sex, religion, education etc. Detailed research proforma was prepared incorporating all the signs and symptoms of the disease Diabetes. Changing life style, lack of exercise, fast foods, improper unbalanced diet, and sedentary life are showing upward trend in India. This has lead to the emergence of Diabetes Mellitus in the region. In the present study a protocol was made to manage the Madhumeha patient by herbal drugs by the applying all the modern parameters. The second type of DM (NIDDM) has a slow, gradual development of symptoms, so that often years pass without the victim being aware of any change. In Avaranajanya /Santarpanajanya Madhumeha the Kapha and Pitta get vitiated due to etiological factors mainly concordant with them, which obstruct the path of Vata causing its provocation & leading to the manifestation of the disease Madhumeha. Here vitiation of Vata occurs due to the Avarana. Total 64 patients were registered, out of which 60 patients were completed the course. They were randomly distributed, 30 patients in Group A (Khadira twak Churna) and 30 patients in Group B (Nimba twak Churna). On analysis of the results, it was found that Group-B (Nimba Twak Churna) was found as the more benefited group. It showed significant as well as highly significant changes with good percentage relief in clinical sign & symptoms of DM. Results: After 60 days treatment the data shows that clinical signs and symptoms of DM like Prabhoot Mootrata (Polyuria) is relieved by 72.2% in Group A & 82.2% in Group B, Aavil Mootrata (Turbidity in Urine) is relieved by 67.00% in Group A & 72.66% in Group B, Pipasa Adhikya (Polydipsia) is relieved by 58.33% in Group A & 70.00% in Group B, Kshuda Adhikya (Polyphagia) is relieved by 53.12% in Group A & 59.00% in Group B, Swedadhikya (Excessive Sweating) is relieved by 40.00% in Group A & 55.55% in Group B, Daurbalyata (Weakness) is relieved by 67.00% in Group A & 72.66% in Group B, Aalasya (Lassitude) is relieved by 29.03% in Group A & 58.49% in Group B, Vibandha (Constipation) is relieved by 30.2% in Group A & 57.49% in Group B, Malavritta Jihwa (Coated Tongue) is relieved by 33.33% in Group A & 50.00% in Group B, Kar Paada Daha (Burning sensation in hand & feet) is relieved by 26.15% in Group A & 61.60% in Group B and Madhurasyata (Sweatness of Mouth)) is relieved by 28.57% in Group A & 50.00% in Group B.

Conclusion: It was observed from the treatment that Nimba twak Churna comparatively provided better relief in clinical signs and symptoms of Diabetes mellitus.

Keywords: Khadira twak churna, Nimba twak churna, Diabetes mellitus, Clinical study.

INTRODUCTION

Diabetes is counted among the five major diseases responsible for morbidity and mortality. Diabetes is counted among the five major diseases responsible for morbidity and mortality. According to W.H.O. in the world 135 million Diabetes mellitus patients were in 1995, now today at least 171 million people worldwide have diabetes; this figurewill reach to 300 million up to 2025. As per recent survey of ICMR out of 100 crores Indian population, 3.2 crores people are known to be diabetic. Besides, nearly same number of diabetics are known to exist, who are unaware that they are suffering from this dreaded disease. Diabetes mellitus has found to be the biggest "silent killer" in the today's world. India has now been declared by W.H.O. as the Diabetes capital of the world.

It is believed that Diabetes mellitus occurs when insulin is not able to metabolize glucose (derailment of glucose metabolism). Here ayurveda believes that it occurs mainly due to medo dusti. This medodusti vitiate mansa, rakta, kleda and ojas. All the dhatus and malas & all three doshas are involved in the disease procedure [1,2]. In Sutra 'Adhyay 17', Charak says that the disease leads due to ojodusti also (when a person eats a rich diet with lack of exercise, it leads to vitiation of oja, which avrits the mutra vaha srotas precipitating to prameha.) [3]. It seems to be the description of autoimmune diabetes mellitus. In Nidan 'Adhyay 4' and Chikitsa 'Adhyay 6' the pathogenesis starts with vitiation of medas⁴.

According to charak the manas doshas – rajas and tamas have a very great adverse effect on the body and three doshas also.

Diabetes mellitus has been classified into Type I and Type II DM. Type I DM patients are usually asthenic and need Insulin for treatment and Type II DM patients are usually obese and are usually managed with oral hypoglycemic agents. So, it may be said that Type I Diabetes mellitus is closer to Dhatukshayajanya Madhumeha while the Type II Diabetes mellitus is closer to Avaranajanya Madhumeha.

Today, the whole world is looking towards Ayurveda with great expectations; they have realized the significance of Ayurveda. According to various Acharyas, Tikta-Kashaya Rasa, Katu Vipaka is the Pramehaghna/ Madhumehaghna [5,6]. Khadira and Nimba are also Tikta-Kashaya in Rasa, & Katu in Vipaka⁷. The hypoglycemic activity of Nimba seed has already approved, so here we want to access the effect of Khadira and Nimba bark in diabetes mellitus.

MATERIALS AND METHODS

Selection of patients

Patients for drug trial were selected from the OPD and IPD of the Govt. Hospitals, after screening them as per Ayurvedic and Modern criteria for Madhumeha. Selection will be carried out according to relevant history,

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sign, symptoms and Laboratory investigations. Total no. of 60 patients were completed the course.

Inclusion Criteria

- Apparently normal individuals between 30 to 70 years of age exposed to various type of stress.
- Diagnosed cases of Diabetes mellitus (Madhumeha).
- Patients with mild hypertension and controlled diabetes mellitus will be included.

Exclusion Criteria

- Patients of age less than 30 years and above 70 years.
- Heart patients and Insulin dependent diabetes mellitus (IDDM) patients.
- Patients taking drugs like corticosteroids, tricyclic antidepressant, cycloheptadine which leads to weight gain.

Plan of Study

Total 64 patients were registered, out of which 60 patients were completed the course. They were randomly distributed in following groups

Group A: 30 patients of this group are treated with Khadira twak

Group B: 30 patients of this group are treated with Nimba twak Churna.

Duration of treatment- 60 days

Route- Orally

Dose- 3 gm twice daily

Laboratorial Investigations

- **Hematological** T.L.C., D.L.C, E.S.R., Hb%
- **Biochemistry** F.B.S., P.P.B.S.
- Urine Examination Routine and microscopic

Criteria of Assessment

The improvement by the therapy was assessed on the basis of classical signs & symptoms. All the features were assigned score depending upon their severity to assess the effect of the drugs objectively. The detail of which is shown below [8].

Scoring pattern for clinical assessment

1. Prabhoot Mootrata [Polyurea]

Frequency of urine

Frequency 4-6 times /24 hours	-	0
Frequency 7-9 times /24 hours	-	1
Frequency 10-12 times /24 hours	-	2
Frequency 13-15 times /24 hours	-	3
Frequency >15 times /24 hours	-	4
Quantity of urine		
Quantity 1.1-2.0 liter		-0
Quantity 2.1-3.0 liter		-1
Quantity 3.1-4.0 liter		-2
Quantity 4.1-5.0 liter		-3
Quantity 5.1-6.0 liter		-4

2. Aavil Mootrata [Turbidity in Urine]

Specific gravity	Urine sugar	Albumin	Total	Score
1020-1025 (0)	Nil (0)	Nil (0)	0	0
1026-1030 (1)	+ (1)	+ (1)	1-3	1
1031-1035 (2)	++ (2)	++ (2)	4-6	2

1036-1040 (3)	+++ (3)	+++ (3)	7-9	3
1041-1045 (4)	++++(4)	++++(4)	10-12	4

3. Pipasa Adhikya [Polydipsia]

Absent (Taking 5-10 glass of water daily)	- 0
Patient is taking 10-15 glass/day & getting satisfaction	- 1
Patient is taking 15-20 glass/day & not getting satisfaction	- 2
Patient is taking 20-25 glass/day & not getting satisfaction	- 3
Patient is unable to have a sound sleep for his/her thirst	- 4

4. Kshuda Adhikya [Polyphagia 2 Chapati/meal-0

2 Chapati/meal-0			0-1=0
3 -4 Chapati/meal-1	Twice meal/day(2)	1 breakfast-1	2-3=1
5 Chapati/meal-2	X Thrice meal/day(3)	+ 2 breakfast-2	4-5=2
6 Chapati/meal-3	> " " "	(4) meal with rice-	1 6-8=3
>7 Chapati/meal-4			> 8=4

Range

5. Swedadhikya [Excessive Sweating]

Normal Perspiration	-0
Mild after doing exertion	- 1
Increased Perspiration after doing little exertion	- 2
Heavy Perspiration after doing little exertion	- 3
Perspiration without exertion	-4

6. Klama [Tiredness]

No Tiredness	-C
Mild after doing work	-1
Tired after doing little work	-2
Works with great difficulty	-3
Having great difficulty for doing little work	-4

7. Aalasya [Lassitude]

Normally active	- (
Hesitate to start work but once started complete it	- 1
Starts but does not complete it	- 2
Doesn't have derive, work under compulsion	- 3
Doesn't starts work	-4

8. Vibandha [Constipation]

Stool passes as per normal schedule	-0
Passes stool with strain, sometimes takes purgative	-1
Passes stool after more than 24 hr, frequently takes purgative	- 2
Passes stool after gap of one day, normal purgative does not work	-3

9. Malavritta Jihwa [Coated Tongue]

No Coating on tongue	-0
Mild Coating on tongue	-1
Moderate Coating on tongue	-2
Heavy Coating on tongue	-3

10. Karpaada Daha [Burning sensation in hand & foot]

Absent	-0
Occasional Kapaada daha	-1
Continuous Karpaada daha	-2
Continuous Karpaada daha & required some medication	-3
Continuous K.P.D. but does not get relief by medication	-4

11. Madhurasyata [Sweetness of Mouth]

No sweetness in mouth	-0
Mild sweetness in mouth	-1
Moderately sweetness in mouth	-2
Always feels sweetness in mouth	-3

Objective Parameter

Assessment of Body Mass Index [B.M.I.]

18.5 - 24.9	=	-
25 - 29.9	=	+
30 - 34.9	=	++
35 - 39.9	=	+++
> 40	=	++++

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Laboratory investigations

1. Haematological Examinations: Hb%, TLC, DLC, ESR

B.T. = A.T. =

2. Bio - Chemical tests: F.B.S., P.P.B.S. and others

B.T. = **A.T.** =

3. Urine Examination: Routine & Microscopic.

B.T. = A.T. =

OBSERVATION AND RESULTS

Maximum number of the patient i.e. were of 51-60 years of age, 35 (58.33%) were male, 85% (51) patients were, middle class are more prone (35%) to Diabetes Mellitus and also upper middle class had (35%), 29 patients (48.33%) were from Sthula Sharira Aakriti, 17 Patients (28.33%) were found with chronicity of 2-5 years, 40 were in habit of taking anti diabetic drugs, 61.66% were having mixed dietary habits, 31 (51.66%) patients were found with Samyak nidra, 48.33% patients were having Madhyam kostha, 18 (30.00%) were having the vishamagni, Madhura Rasa users were 22 (36%) and Lavana rasa users were 15 (25%), 24 patients were taking Tea & Coffee, 60% patients in group A and 50% in Group B were having Stress, 85% patients were living in urban area, maximum numbers of patients were Madhyama Sara, Madhyam Samhanana, Madhyam Pramana Madhyama Satmya and Madhyam Satva, 27 (45.00%) were having mild Hypertension.

Excessive intake of Guru, Snigdha and Madhura Ahara, Avyayama,

Alasya, Samshodhana Akurvatam and Swapna sukham were the most frequent Aharaj and Viharaj Nidanas found in present study. The present study showed that Rasa, Meda, Kleda and Lasika Dushti were found in 100% of the patients. 75.0% of the patients were found to have Rakta Dushti. Each 70.0% of the patients were found to have Mamsa and Vasa Dushti. The Rasavaha and Medovaha Srotasa were found afflicted in all the patients.

Nidana

The above data shows that Guru Ahara, Snigdha Ahara, Madhura Ahara, Avyayama, Alasya, Samshodhana Akurvatam and Swapna sukham were the most frequent Aharaj and Viharaj Nidanas found in present study.

Dushya Dushti

The present study showed that Rasa, Meda, Kleda and Lasika Dushti were found in 100% of the patients. 75.0% of the patients were found to have Rakta Dushti. Each 70.0% of the patients were found to have Mamsa and Vasa Dushti. 71.66% patients reported Majja Dushti and 31.66% Shukra Dushti respectively while Oja Dushti was found in 56.66% of patients.

Sroto dushti

The Rasavaha and Medovaha Srotasa were found afflicted in all the patients. Involvement of rest of the Srotasa are shown in the above table.

Table 01: Showing the incidence of Symptoms of 60 patients of Diabetes mellitus (n =60).

S. No.	Symptoms	Group A	Group B	Total	%
1.	Prabhoot Mootrata (Polyuria)	26	28	54	90.00
2.	Aavil Mootrata (Turbidity in Urine)	28	30	58	96.67
3.	Pipasa Adhikya (Polydipsia)	24	25	49	81.67
4.	Kshuda Adhikya (Polyphagia)	22	23	45	75.00
5.	Swedadhikya (Excessive Sweating)	22	24	46	76.67
6.	Daurbalyata (Weakness)	24	24	48	80.00
7.	Aalasya(Lassitude)	18	20	38	63.33
8.	Vibandha (Constipation)	16	14	30	50.00
9.	Malavritta Jihwa (Coated Tongue)	16	18	34	56.67
10.	Kar Paada Daha(Burning sensation in hand & feet)	12	10	22	36.67
11.	Madhurasyata (Sweetness of Mouth)	12	14	26	43.33

EFFECT OF THERAPIES

Table 02: Show percentage of relief in Symptoms of 60 patients of Diabetes mellitus (n = 60) after two month clinical trial.

Clinical Symptoms	Group A	Group B
Prabhoot Mootrata (Polyuria)	72.2%,	82.2%
Aavil Mootrata (Turbidity in Urine)	67.00%	72.66%
Pipasa Adhikya (Polydipsia)	58.33%	70.00%
Kshuda Adhikya (Polyphagia)	53.12%	59.00%
Swedadhikya (Excessive Sweating)	40.00%	55.55%
Daurbalyata (Weakness)	67.00%	72.66%
Aalasya (Lassitude)	29.03%	58.49%
Vibandha (Constipation)	30.2%	57.49%
Malavritta Jihwa (Coated Tongue)	33.33%	50.00%
Kar Paada Daha (Burning sensation in hand & feet)	26.15%	61.60%
Madhurasyata (Sweetness of Mouth)	28.57%	50.00%

 ${\bf Table~03:~Effect~of~Trial~Drugs~on~Prabhoot~Mootrata~(Polyuria).}$

Croup	Me	ean	Mean diff.	Moon %	N	SD	SE.	т	D	Results
Group	BT	ΑT	Mican uni.	IVICALI /0	14	SD	SE	1		Results
A	2.88	0.80	2.08	72.2	26	0.996	0.199	10.43	< 0.001	HS
В	3.16	0.56	2.60	82.2	28	1.04	0.208	12.49	< 0.001	HS

Note: HS: Highly Significant, S: Significant, IS: Insignificant

Table 04: Effect of Trial Drugs on Aavil Mootrata (Turbidity in Urine)

Crown	Croup Mean		– Mean diff.	Mean %	NI	SD	SE	т	р	Results
Group	BT	AT	- Mean diff. Mean		11	SD	SE	1	r	Resuits
A	3.15	1.03	2.12	67.0	28	1.10	0.217	4.74	< 0.01	S
В	3.19	0.93	2.26	72.66	30	1.05	0.207	12.81	< 0.001	HS

Table 05: Effect of Trial Drugs on Pipasa Adhikya (Polydipsia).

Group	М	ean	Mean diff.	Mean %	N	SD	SE	Т	P	Results
огоцр	BT	ΑT		11104111 / 0	- 1			-	-	11054115
A	2.60	1.08	1.52	58.33	24	0.947	0.197	3.70	< 0.01	S
В	2.5	0.75	1.75	70.00	25	0.846	0.172	10.12	< 0.001	HS

Table 06: Effect of Trial Drugs on Kshuda Adhikhya (Polyphagia).

_	'noun	Me	ean	Mean diff.	Moon %	N	S.D.	S.E.	т	D	Results
•	31 Oup	BT	AT	Mean din.	Mean 70	11	SD	SE	1	r	Results
	A	2.56	1.20	1.36	53.12	22	1.22	0.244	3.57	< 0.01	S
	В	2.65	1.09	1.56	59.00	23	0.945	0.197	7.94	< 0.001	HS

Table 07: Effect of Trial Drugs on Swedadhikya (Excessive Sweating).

Crown	roun Mean		– Mean diff.	Mean %	N	SD	SE	т	D	Results
Group	BT	ΑT	- Mean uni.	Mean 70	11	SD	SE	1	r	Results
A	2.22	1.33	0.88	40.00	22	0.927	0.309	2.87	< 0.02	S
В	2.25	1.00	1.25	55.55	24	0.707	0.25	5.00	< 0.001	HS

Table 08: Effect of Trial Drugs on Daurbalyata(Weakness).

Group	М	an	Mean diff.	Mean %	N	SD	SE	Т	P	Results
	3.16			67.00						S
В	3.17	0.91	2.26	72.66	24	1.05	0.207	12.81	< 0.001	HS

Table 09: Effect of Trial Drugs on Aalasya(Lassitude).

Group Mean		ean	_ Moon diff	- Mean diff. Mean %		SD	SE	т	D	Results
Group	BT	AT	- Mean um.	i. Mean 76 P		SD	SE	1	Г	Results
A	3.1	2.2	0.9	29.03	18	1.65	0.369	2.43	< 0.02	S
В	2.78	1.15	1.63	58.49	20	1.01	0.232	4.03	< 0.01	S

Table 10:Effect of Trial Drugs on Vibandha (Constipation).

Croun	Me	ean	Mean diff.	Moon %	N	cn.	SE.	т	D	Results	
Group	BT	AT	Mean uni.	Mean 70	11	SD	SE	1	r	Results	
A	3.01	2.11	0.60	30.2	16	1.65	0.369	2.43	< 0.02	S	
В	2.75	1.15	1.60	57.49	14	1.01	0.227	5.02	< 0.001	HS	

Table 11: Effect of Trial Drugs on Malavritta Jihwa (Coated Tongue).

Group	M BT	ean AT	Mean diff.	Mean %	N	SD	SE	T	P	Results
A	3.3	2.3	1.00	33.33	16	0.442	0.20	3.07	< 0.01	S
В	2.0	1.00	1.00	50.00	18	0.526	0.242	4.14	< 0.01	S

Table 12: Effect of Trial Drugs on Kar -Paada Daha(Burning sensation in hand & feet).

Group	Mean		- Mean diff.	Mean %	NI	CD.	CE	т	n	Dogulta
	BT	AT	– Mean dill.	Mean 76	N	SD	SE	1	r	Results
A	3.25	2.40	0.85	26.15	12	1.59	0.357	2.37	< 0.02	S
В	2.86	1.09	1.77	61.60	10	1.15	0.245	4.14	< 0.01	S

Table 13: Effect of Trial Drugs on Madhurasyata (Sweetness of Mouth).

Croun	Mean		Mean diff.	Moon 9/	N	CD.	SE.	т	D	Results
Group	BT	AT	wiean uiii.	Micali 70	11	SD	SE	1	г	Results
A	2.15	1.54	0.61	28.57	12	1.12	0.310	1.97	< 0.05	S
В	2.30	1.15	1.15	50.00	14	0.688	0.191	6.04	< 0.001	HS

Effect of Trial Drugs on Hb, TLC, DLC & ESR $\,$

After the routine investigation it was observed that there was insignificant increased in the level of hemoglobin GM percent In-group A 1.84% (T = 1.47, P<0.10), and 2.11%, (T = 1.59, P<0.10) In Group B, after the investigation no significant value was found in any group insignificant improvement in the level of tlc 2.41%, (T = 1.49, P<0.10) IN GROUP A AND 2.44%(T = 1.61, P<0.10) IN Group B. In both groups insignificant change found in the level of DLC, whereas a significant decrease in esr was noticed in Group A AND Group B, GROUP A 9.54%, (T = 1.93, P<0.05), In Group B significant decrease was measured 10.28%, (T = 2.04, P<0.05).

Effect of Trial Drugs on Fasting Blood Sugar and Post Prandial Blood Sugar

After making the investigations it was found that Group A had significant reduction of 1.41%, (t = 2.19, P<0.05); whereas Group B were found with more significant decrease 4.87% (t=4.09, P<0.01) for \mathbf{FRS}

After making the investigations it was found that Group A had significant reduction of 8.85%, (t = 2.91, P<0.02); whereas Group B were found with more significant decrease 9.78% (t=4.41, P<0.01) for **P.P.B.S.**

Effect of Trial Drugs on other investigations

After investigation it was found that Group A and Group B shows insignificant changes in the level of Serum cholesterol, Serum Triglyceride, HDL, SLDL, SVLDL, Serum creatinine and Serum urea.

Overall Effect in Both Groups

Table 14: Overall effect of therapy on 60 patients of Diabetes mellitus (n = 60).

S. No.	Overall Effect	Group A	(n=30)	%	Group B	(n=30)	%
1.	Complete remission	00		00	01		3.33
2.	Marked Improvement	06		20	08		26.66
3.	Moderate Improvement	07		23.33	13		43.33
4.	Mild Improvement	14		46.66	07		23.33
5.	Unchanged	03		10	01		3.33

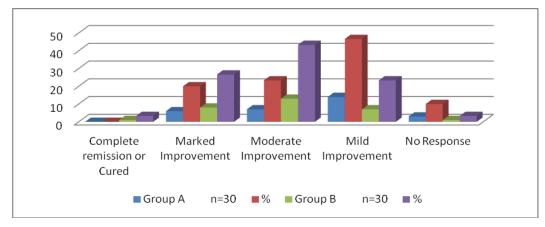


Figure 01: Overall Effect of Therapy.

DISCUSSION

In present study, about observation and result of signs & symptoms, percentage relief, hematological investigations, bio chemistry tests, other investigation and overall effect of therapy we have already discussed in detail in clinical study section. Both the trial drugs show successful improvement to relieve the clinical signs and symptoms of disease. At overall, Marked improvement was observed in 06 (20%) patients of Group A and 08 (26.66) patients of Group B. Moderate improvement was observed in 07 (23.33%) patients of Group A and 13 (43.33%) patients of Group B Mild improvement was observed in 14 (46.66) patients of Group A and 07 (23.33) patients of Group B. **Statistically** Group A shows significant (<0.01) result in most of the clinical symptoms and Group B Shows highly significant (<0.001) result in most of the symptoms.

CONCLUSION

Statistically Group A shows more commonly significant (<0.01) result in most of the clinical symptoms and Group B Shows highly significant (<0.001) result in most of the symptoms. After making the investigations it was found that group A had significant reduction of (P<0.05); F.B.S. and P.P.B.S. whereas Group B were found with more significant decrease (P<0.01) for F.B.S. and P.P.B.S. After investigation it was found that Group A and Group B both shows insignificant changes in the level of routine hematological, Serum cholesterol, Serum Triglyceride, HDL, SLDL, SVLDL, Serum creatinine and Serum urea.

In nutshell, the present study concluded that Group-B (Nimba Twak Churna) was found as the more benefited group. Group A (Khadira Twak Churna) is also gives appreciating and significant results but Group B showed significant as well as highly significant changes with good percentage relief in clinical signs & symptoms of DM.

In case of FBS and PPBS both groups showed significant result whereas Group B showed more significant result than Group A.

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