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Research Article

A COMPARATIVE CLINICAL STUDY OF *NISHADI CHURNA* AND METFORMIN IN THE MANAGEMENT OF *MADHUMEHA* (TYPE-2 DIABETES MELLITUS)

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ABSTRACT

Madhumeha, a *Vataja* subtype of *Prameha* in Ayurveda, has been clinically associated with Type-2 Diabetes Mellitus (T2DM). The escalating prevalence of diabetes in India estimated to affect 80 million individuals by 2030 demands a rigorous evaluation of traditional Ayurvedic therapeutics. *Nishadi Churna*, a classical formulation from Bharat Bhaishajya Ratnakar (Part 3, Verse 3445), comprises *Haridra* (Curcuma longa) and *Amalaki* (*Emblica officinalis*) taken with *Madhu* (honey), all documented *Prameha-nashak* agents. This open randomized controlled clinical trial enrolled 60 patients (age 35–60 yrs) with *Madhumeha*/ Type-2 DM. Group A (n=30) received *Nishadi Churna* 2.2 g/day with *Madhu* as *Anupana* for 3 months; Group B (n=30) received Metformin 500–2500mg/day for 3 months. Both groups showed statistically significant improvement ($p<0.0001$). *Nishadi Churna* demonstrated 77–83% improvement in all clinical parameters, with superior performance in *Karpadadaha/ Supti* (83.67% vs. 57.67%, $p=0.0106$) and *Trushnadhikya* (77.72% vs. 64.44%). Metformin was superior in absolute glycemic reduction (Fasting BSL 97% vs. 78.65%; PPBS 94% vs. 77%). Overall, 83.33% patients achieved good improvement. No adverse effects were recorded with *Nishadi Churna*. The formulation is a safe, cost-effective Ayurvedic alternative for managing *Madhumeha*/T2DM.

INTRODUCTION

Background and Rationale

Diabetes mellitus (DM) is a world-wide population health problem on the rise. India is considered to be one of the most affected countries since the population with diabetes will hit 80 million by 2030[1]. Despite advances in modern pharmacotherapy, existing oral hypoglycaemic agents (OHAs) carry significant adverse effects, including lactic acidosis (metformin), hypoglycaemia (sulfonylureas) and none of them deal with the underlying pathology[2]. The classical Indian medical system called Ayurveda describes *Madhumeha* (a form of *Vataja Prameha*) in detail in the major *Samhitas* (Charaka, Sushruta, Vagbhata).

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Its pathophysiology *(Samprapti)* includes *Vata* and *Kapha doshas* vitiation, *Kleda* (morbid moisture) accumulation and dysfunction of the *Dhatvagni* (metabolic fires) which are closely comparable to insulin resistance and beta-cell dysfunction in Type-2 DM.[3,4,5] According to Bharat Bhaishajya Ratnakar (Part 3, Verse 3445), *Nishadi Churna* is a *Prameha-nashak* (anti-diabetic) preparation. Its constituents- *Haridra* (*Curcuma longa*) and *Amalaki* (*Emblica officinalis*)- are recognized individually as *Kapha pitta shamaka, Kleda-pachaka* and *Rasayana*. The *Anupana* (vehicle), *Madhu* (honey), itself is *Prameha-nashak* in classical literature[6].

MATERIALS AND METHODS

Study Design

An open, randomized, controlled clinical trial was conducted at the Kayachikitsa OPD and IPD of Late Kedari Redekar Ayurvedic Mahavidyalaya, Gadhinglaj. A total of 60 patients were randomized into two groups: Group A (n=30)- *Nishadi Churna* (trial); Group B (n=30)- Metformin (control). Duration of treatment

was 3 months (90 days) with follow-up assessments every 15 days. Institutional Ethics Committee clearance was obtained and written informed consent was taken from all participants prior to enrolment.

Selection Criteria

Inclusion criteria: Age 35–60 years, either sex, any socioeconomic status; presence of *Pratyatma lakshanas* of *Madhumeha- Prabhutmutrata* (polyuria), *Kshudhadhikya* (polyphagia), *Trushnadhikya* (polydipsia), *Karpadadaha/Supti* (burning/tingling feet and hands), *Avilmutrata* (turbid urine); Fasting BSL: 100–200mg/dL; Post-prandial BSL: 150–275mg/dL; newly detected T2DM patients not on any prior pharmacotherapy.

Exclusion criteria: Type-1 DM, gestational diabetes, diabetes insipidus; chronic kidney disease, CAD, PVD, severe neuropathy, retinopathy, or gangrene; patients on insulin or modern OHAs, malignancy, chemotherapy /radiotherapy, surgical or traumatic injuries, or congenital anomalies of the pancreas[7].

Drug Preparation and Administration

Group A- *Nishadi Churna* (Trial Drug): *Haridra* (Curcuma longa, rhizome) and *Amalaki* (Emblica officinalis, fruit) were sourced from an authorized pharmacist. Haridra rhizome was pulverised to fine *Suksham churna*; fresh *Amalaki* fruits were juiced to obtain *Swarasa*; *Haridra churna* was mixed with *Amalaki Swarasa* until *Leedha* (paste) consistency. Dose: 2.2 g (3 *Masha*) per day in divided doses, oral route, 3 months. *Anupana*: *Madhu* (honey). [Ref: Bharat Bhaishajya Ratnakar, Part 3, Verse 3445][6].

Group B- Metformin (Control Drug): Class: Biguanide oral hypoglycaemic agent. Dose: 500–2500mg/day in divided doses, oral route, 3 months. Mechanism: decreases hepatic gluconeogenesis, increases peripheral insulin sensitivity; has low hypoglycaemic risk as monotherapy[8,9].

Assessment Parameters

Subjective parameters were graded on a 0–3 scale: *Prabhutmutrata* (Grade 0: ≤1000ml/day, Grade 3: >2001ml/day), *Kshudhadhikya* (Grade 0: normal to Grade 3: markedly increased appetite), *Trushnadhikya* (Grade 0: 2–3L/day, Grade 3:>5L/day), *Karpadadaha/Supti* (Grade 0: absent Grade 3: affecting daily routine). Objective parameters: *Avilmutrata* (Grade 0: crystal clear; Grade 3: newsprint- unreadable); Urine sugar (Grade 0: absent; Grade 3: >2%); Fasting BSL (Grade 0: 100–125; Grade 3: 176–200mg/dL); Post-Prandial BSL (Grade 0: 150–200; Grade 3: 251–275mg/dL). Overall Illness Grade: Score 1–8 = Mild; 9–16 = Moderate; 17–24 = Severe[10,11]. Subjective and objective parameters were graded on a 0–3 scale as detailed in Tables 1 and 2 below. Overall illness grading was based on composite scores (Table 2a).

Table 1: Subjective Parameters and Gradation Criteria

***Lakshana* (Symptom)**	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**
Prabhutmutrata (Polyuria)	≤1000ml/day	1001–1500ml/day	1501–2000ml/day	>2001ml/day
Kshudhadhikyata (Polyphagia)	Normal (3 meals/day)	Slightly increased (1–2 extra meals)	Moderately increased (2–3 extra meals)	Markedly increased (>3 extra meals)
Trushnadhikyata (Polydipsia)	2–3 litres/24 hrs	3–4 litres/24 hrs	4–5 litres/24 hrs	>5 litres/24 hrs
Karpadadaha/Supti (Burning/Tingling)	Absent	Occasional; not affecting daily routine	Not affecting daily routine but present	Affecting daily routine work

Table 2: Objective Parameters and Gradation Criteria

Parameter	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**
Avilmutrata (turbidity of urine)	Crystal clear fluid	Faintly cloudy/hazy with slight turbidity	Turbidity clearly present; newsprint easily read through tube	Newsprint not easily read through tube
Urine sugar (USL)	Absence of glucose (Nil)	<0.5% glucose (+)	0.5–1.0% glucose (++)	>1–2% glucose (+++)
BSL Fasting (mg/dl)	100–125mg/dl	126–150mg/dl	151–175mg/dl	176–200mg/dl
BSL Post- Prandial (mg/dl)	150–200 mg/dl	201–225 mg/dl	226–250 mg/dl	251–275 mg/dl

Table 2a: Overall Severity Scoring

Overall Score	Severity
1–8	Mild Illness (Grade 1)
9–16	Moderate Illness (Grade 2)
17–24	Severe Illness (Grade 3)

Statistical Analysis

Intra-group comparison (before vs. after treatment) was performed using the Wilcoxon Signed Rank Test. Inter-group comparison (Group A vs. Group B) was performed using the Mann-Whitney U Test. A p-value <0.05 was considered statistically significant; p<0.0001 was considered highly significant.

RESULTS AND DISCUSSION

Demographic Profile

The demographic characteristics of both groups are presented in Tables 3 to 7. The 50–60 years age group was dominant (47%), consistent with the Ayurvedic concept that *Vata* increases progressively with advancing age[12] *(Vriddhavastha),* aggravating the *Vataja* pathogenesis of *Madhumeha*. A high proportion of sedentary occupations corroborates the Ayurvedic *Nidana* of *Avyayama* (lack of exercise) and modern T2DM risk factors. Family history was present in 77% of patients, confirming the *Bija Dosha* (hereditary/ genetic) dimension of *Sahaja Prameha. Vatakaphaja Prakruti* patients (22%) were the most susceptible, consistent with the *Kapha-Vata* pathogenesis of *Madhumeha*.

Table 3: Age-wise Distribution of Patients

Age Group (Yrs)	Group A (n)	A%	Group B (n)	B%	Total (n)	T%
30–40 years	8	26.67	7	23.33	15	25.00
40–50 years	7	23.33	10	33.33	17	28.33
50–60 years	15	50.00	13	43.33	28	46.67
Total	30	100	30	100	60	100

Table 4: Sex-wise Distribution of Patients

Sex	Group A (n)	A%	Group B (n)	B%	Total (n)	T%
Male	15	50.00	16	53.33	31	51.67
Female	15	50.00	14	46.67	29	48.33
Total	30	100	30	100	60	100

Table 5: Diet-wise Distribution of Patients

Diet Type	Group A (n)	A%	Group B (n)	B%	Total (n)	T%
Vegetarian	3	10.00	3	10.00	6	10.00
Non-Vegetarian	10	33.33	10	33.33	20	33.33
Mixed	17	56.67	17	56.67	34	56.67
Total	30	100	30	100	60	100

Table 6: Family History Distribution

Family History	Group A (n)	A%	Group B (n)	B%	Total (n)	T%
Present	23	76.67	23	76.67	46	76.67
Absent	7	23.33	7	23.33	14	23.33
Total	30	100	30	100	60	100

Table 7: *Prakruti*-wise Distribution of Patients

Prakruti	**Group A (n)**	**A%**	**Group B (n)**	**B%**	**Total (n)**	**T%**
Vata (V)	5	16.67	4	13.33	9	15.00
Vatakapha (VK)	6	20.00	7	23.33	13	21.67
Kapha (K)	5	16.67	4	13.33	9	15.00
Vatapitta (VP)	3	10.00	1	3.33	4	6.67
Kaphapitta (KP)	2	6.67	1	3.33	3	5.00
Pittakapha (PK)	5	16.67	7	23.33	12	20.00
Pitta (P)	2	6.67	4	13.33	6	10.00
Others	2	6.67	2	6.67	4	6.67
Total	30	100	30	100	60	100

Effect on Subjective Parameters

Tables 8–11 show the symptom-wise patient distribution before treatment (BT) and after treatment (AT) for each subjective parameter. The intra-group improvement was statistically significant in both groups ($p<0.0001$). *Nishadi Churna* proved to be more effective in *Karpadadaha/Supti* (83.67% vs. 57.67%, $p=0.0106$) and *Trushnadhikya* (77.72% vs. 64.44%), indicating its anti-inflammatory and neuroprotective potential. Metformin was superior in *Prabhutmutrata* (98.19% vs. 88.13%, $p=0.0404$), *Kshudhadhikya* (97.66% vs. 78.16%, $p<0.0001$), and *Avilmutrata* (96.37% vs. 82.09%, $p=0.0304$).

Table 8: Symptom-wise Observation- *Prabhutmutrata* (Polyuria)

	Group A (Trial)		**Group B (Control)**		**Total (n)**		**Total %**	
	BT	**AT**	**BT**	**AT**	**BT**	**AT**	**BT%**	**AT%**
Completely Relieved	0	22 (73.3%)	0	27 (90%)	0	49	0	81.7
Mild Symptoms	5 (16.7%)	8 (26.7%)	7 (23.3%)	3 (10%)	12	11	20	18.3
Moderate Symptoms	22 (73.3%)	0	21 (70%)	0	43	0	71.7	0
Severe Symptoms	3 (10%)	0	2 (6.7%)	0	5	0	8.3	0
Total	30	30	30	30	60	60	100	100

Table 9: Symptom-wise Observation- *Kshudhadhikyata* (Polyphagia)

	Group A (Trial)		**Group B (Control)**		**Total (n)**		**Total %**	
	BT	**AT**	**BT**	**AT**	**BT**	**AT**	**BT%**	**AT%**
Completely Relieved	0	19 (63.3%)	0	28 (93.3%)	0	47	0	78.3
Mild Symptoms	15 (50%)	11 (36.7%)	12 (40%)	2 (6.7%)	27	13	45	21.7
Moderate Symptoms	13 (43.3%)	0	16 (53.3%)	0	29	0	48.3	0
Severe Symptoms	2 (6.7%)	0	2 (6.7%)	0	4	0	6.7	0
Total	30	30	30	30	60	60	100	100

Table 10: Symptom-wise Observation- *Trushnadhikyata* (Polydipsia)

	Group A (Trial)		Group B (Control)		Total (n)		Total %	
	BT	AT	BT	AT	BT	AT	BT%	AT%
Completely Relieved	0	17 (56.7%)	0	12 (40%)	0	29	0	48.3
Mild Symptoms	8 (26.7%)	13 (43.3%)	10 (33.3%)	17 (56.7%)	18	30	30	50
Moderate Symptoms	20 (66.7%)	0	19 (63.3%)	1 (3.3%)	39	1	65	1.7
Severe Symptoms	2 (6.7%)	0	1 (3.3%)	0	3	0	5	0
Total	30	30	30	30	60	60	100	100

Table 11: Symptom-wise Observation - *Karpadadaha/Supti* (Burning sensation/Numbness)

	Group A (Trial)		Group B (Control)		Total (n)		Total %	
	BT	AT	BT	AT	BT	AT	BT%	AT%
Completely Relieved	0	21 (70%)	0	12 (40%)	0	33	0	55
Mild Symptoms	11 (36.7%)	9 (30%)	11 (36.7%)	14 (46.7%)	22	23	36.7	38.3
Moderate Symptoms	18 (60%)	0	18 (60%)	4 (13.3%)	36	4	60	6.7
Severe Symptoms	1 (3.3%)	0	1 (3.3%)	0	2	0	3.3	0
Total	30	30	30	30	60	60	100	100

Effect on Objective Parameters

Tables 12–15 present the parameter-wise distribution before and after treatment for objective measures. The intra-group improvement in both groups was extremely significant ($p<0.0001$). Metformin showed better absolute glycaemic control (Fasting BSL: 97% vs. 78.65%, $p=0.0018$; Post-Prandial BSL: 94% vs. 77%, $p=0.0068$; Urine Sugar: 95.75% vs. 82.05%, $p=0.01$), which indicates that in severe hyperglycaemia, Metformin or combination therapy would be ideal.

Table 12: Objective Observation - *Avilmutrata* (Urine Turbidity)

	Group A (Trial)		Group B (Control)		Total (n)		Total %	
	BT	AT	BT	AT	BT	AT	BT%	AT%
Completely Relieved	0	20 (66.7%)	0	27 (90%)	0	47	0	78.3
Mild Turbidity	10 (33.3%)	10 (33.3%)	6 (20%)	3 (10%)	16	13	26.7	21.7
Moderate Turbidity	19 (63.3%)	0	23 (76.7%)	0	42	0	70	0
Severe Turbidity	1 (3.3%)	0	1 (3.3%)	0	2	0	3.3	0
Total	30	30	30	30	60	60	100	100

Table 13: Objective Observation - Urine Sugar Level

	Group A (Trial)		Group B (Control)		Total (n)		Total %	
	BT	AT	BT	AT	BT	AT	BT%	AT%
Completely Relieved (Nil)	0	0	0	26 (86.7%)	0	26	0	43.3
Mild (+)	0	1 (3.3%)	1 (3.3%)	4 (13.3%)	1	5	1.7	8.3
Moderate (++)	26 (86.7%)	12 (40%)	25 (83.3%)	0	51	12	85	20
Severe (+++)	4 (13.3%)	17 (56.7%)	4 (13.3%)	0	8	17	13.3	28.3
Total	30	30	30	30	60	60	100	100

Table 14: Objective Observation - BSL Fasting

	Group A (Trial)		Group B (Control)		Total (n)		Total %	
	BT	AT	BT	AT	BT	AT	BT%	AT%
Completely Relieved (100–125 mg/dl)	0	16 (53.3%)	0	27 (90%)	0	43	0	71.7
Mild (126–150 mg/dl)	3 (10%)	14 (46.7%)	2 (6.7%)	3 (10%)	5	17	8.3	28.3
Moderate (151–175 mg/dl)	25 (83.3%)	0	26 (86.7%)	0	51	0	85	0
Severe (176–200 mg/dl)	2 (6.7%)	0	2 (6.7%)	0	4	0	6.7	0
Total	30	30	30	30	60	60	100	100

Table 15: Objective Observation - BSL Post-Prandial

	Group A (Trial)		Group B (Control)		Total (n)		Total %	
	BT	AT	BT	AT	BT	AT	BT%	AT%
Completely Relieved (150–200 mg/dl)	0	15 (50%)	0	25 (83.3%)	0	40	0	66.7
Mild (201–225 mg/dl)	2 (6.7%)	15 (50%)	1 (3.3%)	5 (16.7%)	3	20	5	33.3
Moderate (226–250 mg/dl)	25 (83.3%)	0	26 (86.7%)	0	51	0	85	0
Severe (251–275 mg/dl)	3 (10%)	0	3 (10%)	0	6	0	10	0
Total	30	30	30	30	60	60	100	100

Consolidated Symptom-wise Relief Score and Overall Effect of Therapy

Table 16 consolidates the total relief scores and percentage relief across all parameters. Table 17 presents the overall effect of therapy across 60 patients. Across all 60 patients, 83.33% (50/60) achieved good improvement and 16.66% (10/60) achieved moderate improvement. No patient showed deterioration or adverse effects. The mean overall response in Group A was 80.11% and in Group B was 86.92%.

Table 16: Symptom-wise Relief Score and Percentage (Consolidated)

Symptom	Group A (Trial)				Group B (Control)				Better Group
	BT	AT	Diff	% Relief	BT	AT	Diff	% Relief	
Prabhutmutrata	58	8	50	86.20%	55	3	52	94.54%	Group B
Kshudhadhikya	47	11	36	76.59%	50	2	48	96.00%	Group B
Trushnadhikya	50	9	41	82.00%	51	19	32	62.74%	Group A
Karpadadaha/Supti	50	11	39	78.00%	50	22	28	56.00%	Group A
Avilmutrata	51	10	41	80.39%	55	3	52	94.54%	Group B
Urine Sugar	64	14	50	78.12%	63	4	59	93.65%	Group B
BSL Fasting	60	14	46	76.66%	60	3	57	95.00%	Group B
BSL Post-Prandial	60	15	45	75.00%	62	5	57	91.93%	Group B

Table 17: Overall Effect of Therapy in 60 Patients

Type of Improvement	Trial Group A (n)	Control Grp B (n)	Total (n)	Trial A (%)	Control B (%)	Total (%)
Good Improvement (Above 75%)	23	27	50	76.66	90.00	83.33
Moderate Improvement (50–75%)	7	3	10	23.33	10.00	16.66
Mild Improvement (25–50%)	0	0	0	0.00	0.00	0.00
No Improvement (0–25%)	0	0	0	0.00	0.00	0.00
Total	**30**	**30**	**60**	**100**	**100**	**100**

Statistical Analysis of Results

Table 18 presents the intra-group statistical analysis using the Wilcoxon Signed Rank Test and Table 19 presents the inter-group comparative analysis using the Mann-Whitney U Test.

Table 18: Intra-group Statistical Analysis (Wilcoxon Signed Rank Test)

Parameter	Group	Mean BT	SD BT	Mean AT	SD AT	% Relief	p-value
Prabhutmutrata	Group A	1.933	0.5208	0.2667	---	88.13	<0.0001
	Group B	1.833	0.5307	0.0667	0.2537	98.19	<0.0001
Kshudhadhikya	Group A	1.567	0.6261	0.3667	0.4901	78.16	<0.0001
	Group B	1.667	0.6065	0.0667	0.2537	97.66	<0.0001
Trushnadhikya	Group A	1.800	0.5510	0.4333	0.5040	77.72	<0.0001
	Group B	1.700	0.5350	0.6330	0.5560	64.44	<0.0001
Karpadadaha/Supti	Group A	1.667	0.5467	0.3000	0.4660	83.67	<0.0001
	Group B	1.666	0.5467	0.7333	0.6920	57.67	<0.0001
Avilmutrata	Group A	1.700	0.5350	0.3330	0.4795	82.09	<0.0001
	Group B	1.833	0.4611	0.1000	0.3051	96.37	<0.0001
Urine Sugar	Group A	2.133	0.3457	0.4667	0.5713	82.05	<0.0001
	Group B	2.100	0.4026	0.1330	0.3457	95.75	<0.0001
BSL Fasting	Group A	2.000	0.4549	0.4667	0.5074	78.65	<0.0001
	Group B	2.000	0.3714	0.1000	0.3051	97.00	<0.0001
BSL Post-Prandial	Group A	2.000	0.4549	0.5000	0.5085	77.00	<0.0001
	Group B	2.067	0.3651	0.1667	0.3790	94.00	<0.0001

BT = Before Treatment; AT = After Treatment; SD = Standard Deviation. Wilcoxon Signed Rank Test used for intra-group comparison. Level of significance: $p < 0.05$.

Table 19: Inter-group Comparative Statistical Analysis (Mann-Whitney U Test)

Parameter	Group A Mean AT	Group B Mean AT	Mann-Whitney Z	p-value
Prabhutmutrata	0.2667	0.0667	360	0.0404 (Sig)*
Kshudhadhikya	0.3667	0.0667	12	<0.0001 (H.Sig)**
Trushnadhikya	0.4333	0.6330	368	0.1702 (NS)
Karpadadaha/Supti	0.3000	0.7333	297	0.0106 (Sig)*

Avilmutrata	0.3330	0.1000	345	0.0304 (Sig)*
Urine Sugar	0.4667	0.1330	313	0.0100 (Sig)*
BSL Fasting	0.4667	0.1000	285	0.0018 (H.Sig)**
BSL Post-Prandial	0.5000	0.1667	300	0.0068 (H.Sig)**

Significance Key: * $p < 0.05$ = Significant; ** $p < 0.001$ = Highly Significant; NS = Not Significant

DISCUSSION

The formulation acts on the core *Samprapti* through: (1) *Kleda pachana* (metabolising abnormal moisture)- *Haridra's Katu rasa* and *Ushna virya* desiccate and digest the *Kleda* accumulating in Meda and *Mamsa dhatu*; (2) *Kapha-Vata shamana*- the combined *Tiktha-Katu-Amla rasa* complex of *Haridra* and *Amalaki* pacifies the primary *Doshas*; (3) *Dhatvagni Deepana- Amalaki's Rasayana* property restores metabolic fires, improving *Oja* (functional essence); (4) *Anupana* enhancement- *Madhu's Yogavahi* (vehicle-enhancing) property potentiates drug absorption and adds independent *Prameha-nashak* action.

Curcumin (active constituent of Haridra) stimulates GLUT-4 translocation, improves pancreatic beta-cell function, inhibits NF-κB-mediated inflammation, and reduces oxidative stress[13]. Emblicanin A and B (*Amalaki's* polyphenols) inhibit alpha-glucosidase (similar to Acarbose mechanism), delay carbohydrate absorption, and protect beta cells from oxidative damage via antioxidant (Vitamin C) activity[14]. Gallic acid in *Amalaki* improves insulin sensitivity. *Madhu* has a low glycaemic index and fructose-mediated slower insulin response.

Nishadi Churna outperformed Metformin significantly in *Karpadadaha/Supti* (83.67% vs. 57.67%, p=0.0106) and *Trushnadhikya* (77.72% vs. 64.44%). These advantages could be attributed to the anti-inflammatory and neuroprotective effect of curcumin *(Haridra)* and the *Sheeta virya* of *Amalaki*. Metformin has no direct neuroprotective mechanism.

CONCLUSION

Nishadi Churna demonstrates statistically significant ($p<0.0001$) blood glucose-reducing activity in *Madhumeha* (Type-2 Diabetes Mellitus), achieving 77–83% clinical improvement across all parameters within a 3-month treatment period. *Vatakaphaja Prakruti* individuals aged >50 years with a sedentary lifestyle constitute the highest risk demographic for *Madhumeha*. The formulation is superior to Metformin in managing *Karpadadaha/Supti* (neuropathic symptoms) at 83.67% vs. 57.67% (p=0.0106), making it uniquely valuable for diabetic peripheral neuropathy. It shows comparable efficacy to Metformin in reducing *Trushnadhikya* (polydipsia). Metformin demonstrates superior performance in absolute glycaemic reduction (FBS 97% vs. 78.65%; PPBS 94% vs. 77%), indicating that for severe hyperglycaemia, combination therapy may be optimal. No adverse effects, toxicity, or hypoglycaemic episodes were observed with *Nishadi Churna*, affirming its safety profile. Larger, multi-centric RCTs with HbA1c as primary outcome, HPTLC/HPLC standardization of *Nishadi Churna*, longer follow-up (6–12 months), and combination studies are recommended to further establish clinical utility and achieve mainstream integration.

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