A Pilot Study on Nisha Triphaladi Yoga in Apatyanimittaja Madhumeha (Type 2 Diabetes Mellitus): A Single-Arm Pre–Post Quasi-Experimental Evaluation

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Abstract
Background: Type 2 Diabetes Mellitus (T2DM), a common growing global health issue, inadequately controlled despite various advances in modern science or pharmacotherapy, which carries lacunae like side effect and long term dependency. Ayurveda correlates T2DM with *Madhumeha*, disorder with *kapha-medo* predominant, described under *Ashta-Mahagada*. *Nisha Triphaladi Yoga* is a classical formulation mentioned for *Prameha*, yet scientific evidence for its efficacy in early T2DM remains limited. This study aims to address this gap and evaluate its effect on subjective symptoms as well as RBS levels. Objective: Was to evaluate the effect of *Nisha Triphaladi Yoga* on subjective Ayurvedic parameters as well as Random Blood Sugar (RBS) in patients with T2DM. Methods: A single-arm interventional clinical study was conducted on 30 participants diagnosed with *Apatyanimittaja Madhumeha. Nisha Triphaladi Yoga* was administered for a period of 90 days. Assessment carried out was symptom grading (*Bahumutrata, Atikshudha, Karapada Daha, Suptata*) and RBS at baseline and after treatment. Data were analysed using paired t-tests and Wilcoxon signed rank test. Results: Marked improvement was observed among subjective symptoms. *Bahumutrata* reduced from 1.70 to 0.30 ($p < 0.0001$), *Atikshudha* from 1.65 to 0.30 ($p < 0.0001$) *and Karapada Daha/Suptata* from 1.65 to 0.35 ($p < 0.0001$). Mean RBS reduced from 227.00 mg/dl to 153.80 mg/dl ($p < 0.0001$). No adverse events were noted. Conclusion: *Nisha Triphaladi Yoga* demonstrated marked improvement in early-stage T2DM (*Apatyanimittaja Madhumeha*) with reduction in symptoms as well RBS ranges. Intervention was safe and well tolerated. Further larger controlled trials are needed in order to validate these findings.

Keywords: *Atikshudha, Bahumutratha, Nisha Triphaladi Yoga*, Quasi-Experimental Study, RBS, Type 2 Diabetes Mellitus

1. Introduction

Type 2 diabetes mellitus (T2DM), a most prevalent form of diabetes, accounting for approximately 90% of cases worldwide, with its global burden affecting around 462 millions individuals accounting 6.28% of worlds total population (1). Development of T2DM is influenced by various factors including age, gender, ethnicity, lifestyle habits and most importantly genetic predisposition with twin studies showing a concordance rate of 35–60% commonly affecting peoples of age group 35-60 years of age (2). Modern diagnosis based mainly on plasma glucose measurements and conventional management focuses on pharmacological interventions like insulin and oral hypoglycemic agents. However, may produce adverse events and have limited long-term effectiveness in preventing complications (3,4).

In Ayurveda, *Madhumeha*, a disorder involving *kapha-pradhana medodusti* (Kapha-dominant adipose-tissue dysfunction), leading to vitiation of *mamsa* (muscle tissue), *rakta* (blood), *kleda* (body fluids) and *ojas* (vital essence), resulting in excessive urination, tissue debility along with *Ojokshaya* (depletion of vital strength/immunity) (5,6). *Apatyanimittaja Madhumeha*, mostly associated with obesity and *kapha-/meda* increasing lifestyle factors, primarily involves *Basti* region in its pathogenesis. *Sushruta* classifies *Prameha* as one among *Ashtamahagadas*, highlighting its chronic and progressive nature (7,8).

*Nisha Triphaladi Yoga***,** described in *Yogaratnakara*, Formulation consists of *Haridra* (*Curcuma longa*), *Daruharidra* (*Berberis aristata*), *Amalaki* (*Phyllanthus emblica*), *Haritaki* (*Terminalia chebula*) and *Bibhitaki* (*Terminalia bellirica*) and possesses *laghu* (light) and *ruksha* (dry) qualities, balancing *kapha* and *meda* (adipose tissue/fat) through *Deepana* (metabolic enhancing), *Pachana* (digestive) and *Medohara* (fat reducing) actions (9). Previous studies on this formulation are limited, and there is a lack of high-quality clinical evidence evaluating its efficacy in early-stage T2DM.

Aim and Objective: Hence, this study was undertaken to assess the safety and clinical effectiveness of *Nisha Triphaladi Yoga* in managing *Apatyanimittaja Madhumeha*, using both subjective Ayurvedic parameters and objective biochemical outcomes.

2. Materials and Methods

2.1 Participants

A single group pretest and posttest quasi-experimental pilot clinical study was conducted on 30 participants diagnosed with *Apatyanimittaja Madhumeha* (Type 2 Diabetes Mellitus). Individuals of either gender, aged 40 to 60 years, with a recent diagnosis of *Madhumeha* (less than one year) and presenting with classical clinical features such as *Prabhuta Mutrata, Avila Mutrata, Atikshudha, Karapada Daha* and *Suptata* were included. Participants were eligible only if they had baseline hyperglycemia (RBS > 200 mg/dl) while continuing their stable anti-diabetic medications.

Participants were excluded if they were younger than 40 years or older than 60 years, had chronic or long-standing *Madhumeha* with complications, or suffered from major systemic illnesses such as cardiac disorders, renal impairment, hepatic disease, neurological conditions or any other illness requiring separate medical management. Pregnant and lactating women were also excluded.

Study received approval from Institutional Ethical Committee of Shri Gavisiddeswara Ayurvedic Medical College, Hospital and Research Centre, Koppal and trial was prospectively registered under CTRI No. REF/2024/11/095388 dated 27/11/24. Participants were recruited from the outpatient and inpatient departments of the institution between December 2024 and February 2025. Written informed consent was obtained from all participants prior to enrolment, and nature and purpose of the study were clearly explained to them.

2.2 Study Design

This research was conducted as a single-group, pretest–post test quasi-experimental pilot clinical study involving 30 patients with *Apatyanimittaja Madhumeha* (Type 2 Diabetes Mellitus), with no control or comparator group included. Study aimed to evaluate changes in glycemic values and clinical symptoms before and after administering *Nisha Triphaladi Yoga* for 90 days. Study was carried out at Shri Gavisiddeswara Ayurvedic Medical College, Hospital and Research Centre, Koppal, Karnataka, and participants were drawn from patients diagnosed with Type 2 Diabetes Mellitus attending the hospital. Patients were selected through non-random, purposive sampling based on predefined inclusion and exclusion criteria, and no randomization or allocation concealment procedures were undertaken as this was a pilot feasibility study. Total sample of 30 participants was considered as appropriate based on pilot study norms, with study mainly focusing on evaluating within group changes rather than between group differences. Sample size was calculated based on data from a previous study in which Group 1 had an ISI scale Mean ± SD of 7.60 ± 3.09, and a superiority margin of 20% (1.52) was applied. With an expected mean of 6.08 for Group 2, a significance level of 0.05, and a power of 0.8,
Formula Using Mean Difference:

$$n1 = n2 = 2\frac{(Z_\alpha + Z_\beta)^2\sigma^2}{(\delta)^2}$$

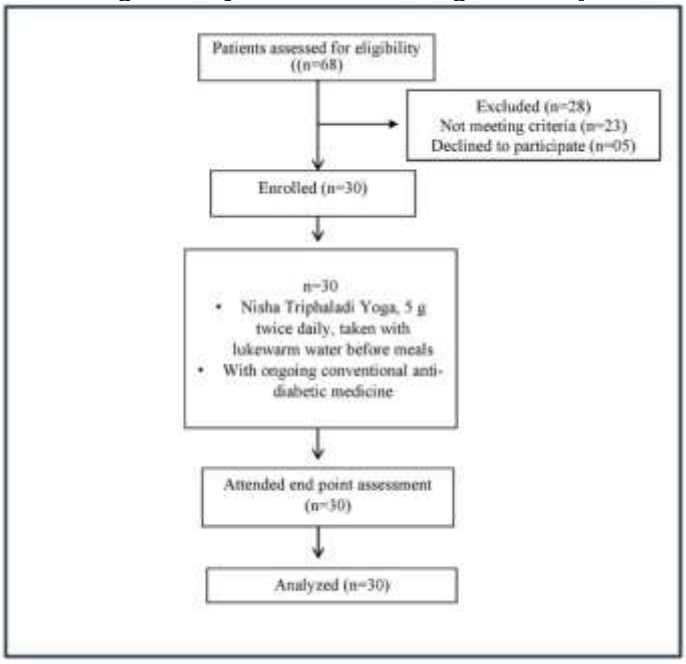
$$Z_\alpha = 1.96,\ \alpha = TypeIerrorat\ 5\% \quad at\ both\ sides\ two\ tailed\ , Z_\beta = 0.84\ = Powerat\ 80\%$$

Calculated sample size based on the formula n = 2 ((Zα + Zβ)² σ²) / (δ²) using values from a previous study (Mean ± SD = 7.60 ± 3.09, superiority margin = 1.52, Zα = 1.96, Zβ = 0.84) yielded an approximate requirement of 32 participants. As this study was designed as a single-group pilot study, a practically feasible sample size of 30 participants was selected.

2.3 Diagnosis, Inclusion and Exclusion Criteria

Diagnosis in this study primarily focused on *Apatyanimittaja Madhumeha* as described in classical Ayurvedic texts; therefore, Ayurvedic clinical features formed main diagnostic criteria. Patients were assessed based on classical symptoms such as *Prabhuta Mutrata, Avila Mutrata, Atikshudha, Karapada Daha* and *Suptata,* and grading of these symptoms was performed as per Ayurvedic assessment guidelines. Since the main objective of study was the Ayurvedic evaluation and management of *Madhumeha* rather than a biomedical categorisation of Type 2 Diabetes Mellitus, investigations like HbA1c were not included. However, Random Blood Sugar (RBS) was recorded, and a value above 200 mg/dl (10) was taken in accordance with American Diabetes Association criteria to ensure baseline biochemical confirmation of hyperglycemia. All investigations were conducted at the clinical laboratory of Shri Gavisiddeswara Ayurvedic Medical College, Hospital and Research Centre, Koppal. Participants between 40 and 60 years of age, recently diagnosed with *Madhumeha* (less than one year), presenting with above classical features and fulfilling the hyperglycemia criterion, were included in the study. Individuals below 40 or above 60 years, those with chronic or complicated *Madhumeha*, or those suffering from systemic illnesses such as cardiac, renal, hepatic or neurological disorders requiring separate clinical attention were excluded. Pregnant and lactating women were also not considered for enrolment (figure 1).

Fig.01: Subject flowchart through the study



2.4 Assessment Criteria and Follow-ups

Assessment was performed using both Ayurvedic and biochemical parameters, with primary emphasis on the classical features of *Apatyanimittaja Madhumeha*. Subjective parameters (table 1), including *prabhuta mutrata*, *atikshudha*, *karapada daha* and *suptata*, were graded at baseline and during each follow-up according to a grading system developed specifically for this study. Objective evaluation included random blood sugar (RBS) measurements, recorded on 0th, 30th, 60th, and 90th days, to monitor hyperglycemia. HbA1c testing was not conducted, as the primary focus of the study was management of *Madhumeha* according to Ayurvedic principles rather than classical Type 2 Diabetes Mellitus.

As this study aims to identify a pre and post treatment changes, detailed evaluation of all parameters was carried out specifically before treatment (0th day) and after completion of treatment (90th day) to determine overall effect of intervention. Follow-up assessments at 30-day intervals were also carried out just to monitor changes in symptoms, treatment compliance and any adverse events. All findings were documented systematically to evaluate outcomes of the intervention

Table 1: Grading of Subjective Parameters in *Apatyanimittaja Madhumeha*

Symptoms	**Grade**	**Interpretation**
***Bahumutrata* (11)**	0	Up to 5 times/day & 0-1 times/night
	1	6-8 times/day & 2-3 times/night
	2	More than 8 times/day & 3-4 times/night
***Atikshudha* (12)**	0	Normal
	1	Increased, but can tolerate
	2	Increased, but cannot tolerate without consuming food
***Karapada Daha* and *Suptata* (13)**	0	Absent
	1	Slightly present
	2	Present

2.5 Intervention

All enrolled participants given with *Nisha Triphaladi Yoga*, classical Ayurvedic polyherbal formulation described by *Yoga Ratnakara*, (9) for a period of 90 days. Medicine was administered in its *churna* form, with a dosage of 5 g twice daily, to be taken with lukewarm water and before meals. Formulation consists of *Haridra* (*Curcuma longa*), *Daruharidra* (*Berberis aristata*), *Amalaki* (*Phyllanthus emblica*), *Haritaki* (*Terminalia chebula*) and *Bibhitaki* (*Terminalia bellirica*) in equal proportions (table 2).

Raw drug were procured from institutional SJAMC Pharmacy and prepared according to classical Ayurvedic methods mentioned in API. Qualitative analysis was performed following API standards which includes microscopic assessment, physico-chemical evaluation (ash value, foreign matter, water and alcohol extractives, loss on drying) alon with preliminary phytochemical screening.

Table 2: Constituents of the *Nisha Triphaladi Yoga* with Botanical Identity, Part Used, Ratio and *Rasa-Panchaka.*

S. No.	Constituent	Botanical/Latin Name	Part Used	Ratio	*Rasa* (Taste)	*Guna* (Quality)	*Virya* (Potency)	*Vipaka* (Post-digestive)	*Prabhava* / Specific Action
1	*Haridra*	*Curcuma longa*	Rhizome	1 Part	*Tikta, Katu*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Rakta Shodhana, Pittaghna*
2	*Daruharidra*	*Berberis aristata*	Rhizome	1 Part	*Tikta, Kashaya (Kashaya* predominant*)*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Pittaghna, Krimighna*
3	*Amalaki*	*Phyllanthus emblica / Emblica officinalis*	Fruit	1 Part	*Pancha Rasa (Madhura, Amla, Tikta, Katu, Kashaya)*	*Laghu, Ruksha, Sheeta*	*Sheeta*	*Madhura*	*Rasayana, Vayasthapana*
4	*Bibhitaki*	*Terminalia bellirica*	Fruit	1 Part	*Kashaya* (predominant), *slight Tikta*	*Laghu, Ruksha*	*Ushna*	*Madhura*	*Anulomana, Kapha-Pittahara*
5	*Haritaki*	*Terminalia chebula*	Fruit	1 Part	*Pancha Rasa (*all except *Lavana), Kashaya* predominant	*Laghu, Ruksha*	*Ushna*	*Madhura*	*Anulomana, Rasayana*

2.6 Statistical Analysis

Statistical analysis were carried out using SPSS software. Continuous variables which includes Random Blood Sugar (RBS) and subjective symptom scores (*Bahumutrata, Atikshudha, Karapada Daha* and *Suptata*), were recored as mean ± standard deviation.

Within group comparisons of pre and post intervention values was carried out using paired t-test for normally distributed data while Wilcoxon signed-rank test for non-normally distributed data. A p-value of less than 0.05 was considered as statistically significant.

All results were analysed to assess the effect of Nisha Triphaladi Yoga on both biochemical and Ayurvedic clinical parameters before (0th day) and after (90th day) the intervention.

3. Results and Observations

3.1 Demographic and Baseline Characteristics

A total of 30 participants completed study. Majority of patients were aged between 45 and 60 years. Among this study population 60% was female while 40% were male. In terms of religion, 66% were Hindu while 34% were Muslim. Occupationally, 45% were businessmen, 35% were female farmers, and 20% were housewives. Socio-economically, 60% belonged to middle class. Only 10% reported a positive family history of diabetes, and 70% followed a non-vegetarian diet. *Prakriti* assessment revealed that 50% of participants had *Vatapitta* prakriti. Most subjects (75%) had *Mrudhu kostha*, and 40% exhibited *Agni sama* at baseline. (table 2)

Table 2: Demographic and Baseline Characteristics of Study Participants (n = 30)

Variable	Category	n (%)
Age (years)	45–60 years	30 (100)
Gender	Female	18 (60)
	Male	12 (40)
Religion	Hindu	20 (66)
	Muslim	10 (34)
Occupation	Businessmen	14 (45)
	Female farmers	11 (35)
	Housewives	5 (20)

Socio-economic status	Middle class	18 (60)
	Others	12 (40)
Family history of diabetes	Present	3 (10)
	Absent	27 (90)
Diet pattern	Non-vegetarian	21 (70)
	Vegetarian	9 (30)
Prakriti	*Vatapitta pradhana*	15 (50)
	Others	15 (50)
Kostha	*Mrudu*	23 (75)
	Others	7 (25)
Agni	*Sama*	12 (40)
	Others	18 (60)

3.2 Effect of Intervention on Subjective Parameters

Subjective symptoms of *Bahumutrata, Atikshudha, Karapada Daha* and *Suptata* were graded using the study-specific grading system described in Table 3-6 and presented in figure 2. Pre- and post-treatment comparison revealed significant improvement in all subjective parameters.

3.2.1 Effect of Intervention on *Bahumutrata*

Bahumutrata showed a decrease in mean score from 1.70 before treatment to 0.30 after treatment (mean difference 1.40; $t = 12.457$; $p < 0.0001$), reflecting an 82.35% improvement from baseline to day 90 and indicating highly effective symptomatic relief (table 3).

Table 3. Effect of Intervention on *Bahumutrata*

Parameter	Baseline (Mean ± SD)	90th Day (Mean ± SD)	% Change	p-value	Test Used	Test Value	df	Remark
Bahumutrata	1.70 ± 0.50	0.30 ± 0.12	82.35%	<0.0001	Paired t-test	t = 12.457	29	Marked improvement

3.2.2 Effect of Intervention on *Atikshudha*

Atikshudha showed improvement from a mean of 1.65 at baseline to 0.30 after treatment (mean difference 1.35; $t = 12.337$; $p < 0.0001$), corresponding to an 81.82% reduction, indicating a statistically significant and clinically meaningful decrease in excessive hunger (table 4).

Table 4. Effect of Intervention on *Atikshudha*

Parameter	Baseline (Mean ± SD)	90th Day (Mean ± SD)	% Change	p-value	Test Used	Test Value	df	Remark
Atikshudha	1.65 ± 0.49	0.30 ± 0.11	81.82%	<0.0001	Paired t-test	t = 12.337	29	Marked improvement

3.2.3 Effect of Intervention on *Karapada Daha* & *Suptata*

Karapada Daha and *Suptata* showed a reduction in mean score from 1.65 before treatment to 0.35 after treatment (mean difference 1.30; $t = 12.365$; $p < 0.0001$), reflecting a 78.79% improvement and demonstrating consistent, significant symptomatic relief following the intervention (table 5).

Table 5. Effect of Intervention on *Karapada Daha* & *Suptata*

Parameter	Baseline (Mean ± SD)	90th Day (Mean ± SD)	% Change	p-value	Test Used	Test Value	df	Remark
Karapada Daha & Suptata	1.65 ± 0.47	0.35 ± 0.11	78.79%	<0.0001	Paired t-test	t = 12.365	29	Marked improvement

3.3 Effect of Intervention on Objective Parameter (RBS)

Mean RBS level showed a marked reduction in its mean from 227.00 mg/dl at baseline to 153.80 mg/dl after 90 day treatment period (mean difference 73.20; $t = 19$; $p < 0.0001$). This signifies a substantial improvement in biochemical marker of hyperglycemia (table 6).

Table 6. Effect of Intervention on RBS

Parameter	Baseline (Mean ± SD)	90th Day (Mean ± SD)	% Change	p-value	Test Used	Test Value	df	Remark
RBS (mg/dl)	227.00 ± 34.88	153.80 ± 7.80	32.27%	<0.0001	Paired t-test	t = 19.000	29	Significant reduction

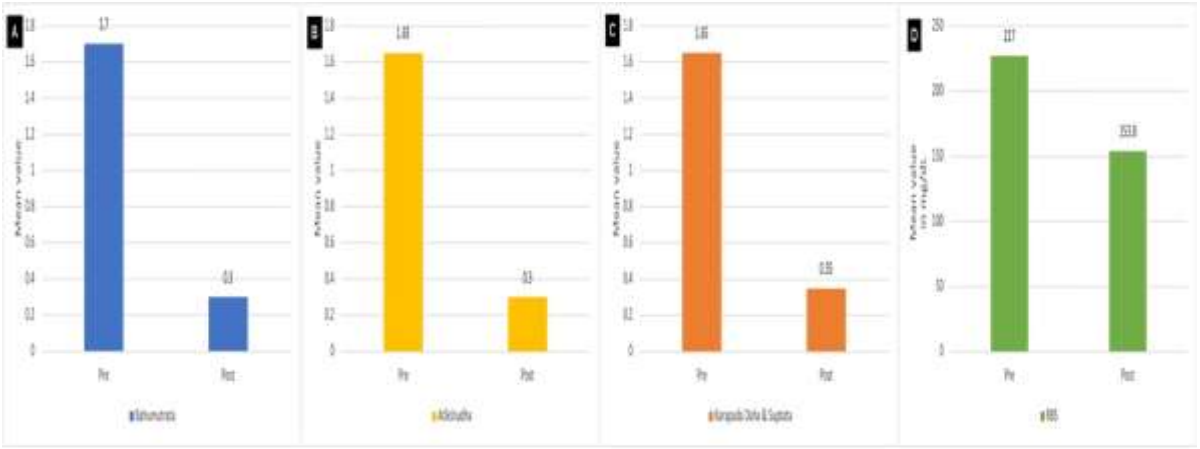


Figure 2: Changes in Subjective parameters and RBS Levels Before and After Treatment (A: *Bahumutrata*, B: *Atikshudha*, C: *Karapada Daha* & *Suptata*, D: RBS)

These findings indicate a marked reduction in the severity of subjective symptoms following administration of *Nisha Triphaladi Yoga.*

3.4 Safety and Adverse Events

No adverse drug reactions or serious events was noted during whole study period. All participants tolerated *Nisha Triphaladi Yoga* well suggesting its safety over 90 days of administration.

3.5 Adherence, Tolerability and Dropouts

Participant adherence to intervention was high monitored through medicine diary with all 30 subjects completing complete 90 day study period as instructed. Formulation was welltolerated without any adverse effects that required discontinuation. No dropouts occurred during whole study duration, highlighting good acceptability and compliance with *Nisha Triphaladi Yoga*.

3.6 Summary of Findings

In short, *Nisha Triphaladi Yoga* produced marked improvements in both subjective Ayurvedic parameters as well as objective biochemical parameter (RBS). Intervention was well tolerated and demonstrated promising therapeutic potential in management of *Apatyanimittaja Madhumeha*. Detailed pre and post treatment statistical analyses, including percentage change and clinical remarks are described in Tables 3–6 and in figure 2.

4. Discussion

Current clinical study was carried out to evaluate the effectiveness of *Nisha Triphaladi Yoga*, classical formulation mentioned by *Yoga Ratnakara* in the management of *Apatyanimittaja Madhumeha*. Total of 30 participants completed intervention and findings demonstrated significant improvement across subjective Ayurvedic parameters as well as objective biochemical outcomes without any adverse events during intervention period.

Demographic profile of study population stated that most participants belonged to the middle age group (45–60 years) which aligns with natural epidemiological trend of *Madhumeha*, as metabolic derangements as well sedentary lifestyle factors become more prominent in this age. Predominance of *Vatapitta prakriti* and *Mrudhu kosta* among participants is also consistent with Ayurvedic principles as *Madhumeha* is described as a condition in which *Vata* becomes aggravated due to the long-standing vitiation of *Pitta* and *Kapha* along with depletion of *Ojas* and *Meda dhatu* in forming its *samprapti* (pathology).

4.1 Effect on Subjective Parameters

Marked reductions was reported in symptoms which includes *Bahumutrata*, *Atikshudha*, *Karapada Daha* as well as *Suptata*. Which are important clinical markers of *Madhumeha* mentioned in classical texts including *Charaka Samhita* and *Yogaratnakara*. Observed improvement can be attributed to *Lekhana* (scrapping), *Kapha–Pitta shamaka*, *Vata anulomana* and *Rasayana* properties of the drug.

- *Haridra* (*Curcuma longa*) possesses *Tikta-Katu rasa*, *Laghu-Ruksha guna*, and *Kaphahara* actions that help reduce excessive urination and improve glucose metabolism (14,15).
- *Triphala* acting as *Rasayana*, supports cleansing of *Srotas* thereby improving *Agni* and stabilising (*kshudha*) hunger levels and reducing neuropathic symptoms like as *daha* and *suptata* (16).
- The combined formulation enhances *Agni*, regulates *Meda dhatu*, and strengthens *Vata*, thereby breaking the pathophysiological cycle of *Madhumeha* (16-18).

Progressive improvements in subjective symptoms within 90 days reflect progressive pacification of doshas and restoration of *Dhatu samyata*.

4.2 Effect on Blood Sugar (RBS)

Marked reduction in RBS mean from 227.00 mg/dl to 153.80 mg/dl ($p < 0.0001$) highlights strong antihyperglycemic potential of *Nisha Triphaladi Yoga*. Previous experimental and clinical studies have already established its hypoglycemic action of turmeric (19,20) as well as *triphala* (18). This synergy in this combination may enhance:

- Glucose utilization at cellular level
- Reduction in insulin resistance
- Improvement in hepatic metabolic functions

From an Ayurvedic perspective, the drug acts primarily through improving *Dhatwagni*, correcting *Kapha avarodha*, and enhancing peripheral tissue response, which collectively restores the functional capacity of *Meda dhatu*. This reduction in RBS level also corresponds with improvements in classical symptoms ensuring holistic action of the formulation.

4.3 Comparison with Previous Literature

Previous literature evaluating single herbs like *Haridra*, *Amalaki* or *Haritaki* have shown beneficial effects in achievibg glycemic control (21). Also studies on *Triphala churna* reported significant improvements in fasting as well postprandial blood sugar levels (22). Present study further supports these findings and further validates efficacy of the combined classical formulation which is *Nisha Triphaladi Yoga* as mentioned by *Yogaratnakara*, which is specifically indicated in *Madhumeha* condition in literature. Multidimensional effect observed in this study spanning metabolic, neurological and systemic symptoms suggests superiority of polyherbal formulations due to its synergistic action.

4.4 Safety Profile

No adverse events was noted during whole study period, suggesting that *Nisha Triphaladi Yoga* is safe as well as well tolerated when administered in therapeutic doses for 90 days. This aligns with the long established safety profile of its individual ingredients in classical Ayurvedic practice.

4.5 Strengths

Strengths include:

- Use of classical Ayurvedic diagnostic criteria relevant to *Madhumeha*.
- Structured grading of subjective symptoms for quantitative assessment.
- A 90-day follow-up, which is adequate to observe metabolic changes.
- Strong statistical significance across both subjective and objective outcomes.

4.6 Limitations

This study has several limitations. Firstly sample size of the study was relatively small (n = 30), hence, there is a risk of a lack of statistical power and imprecision around estimates of effects. Secondly study design being a pre-post single-arm clinical trial without control group, natural glucose fluctuations, placebo effect, and/or regression to mean may have confounded results. Thirdly we did not undertake assessments like HbA1c, lipid profile or markers of insulin resistance as we were focussed primarily on the classical Ayurvedic diagnosis of *Madhumeha* and not merely bio-medical diagnosis of T2DM. Additionally, though lifestyle and dietary habits of trial participants were noted, no attempt were made to strictly control them. Hence they may have influenced as confounders. And lastly, we only assessed short term outcomes (90 days) and medium to long-term sustainability of observed benefits is not known.

4.7 Generalisability

Findings of current study may be generalized to *apatyanimittaja Madhumeha* patients of similar demography as seen in this study especially middle aged patients with *Vatapitta prakriti* and also importantly moderate metabolic derangement. Generalizability of current findings to larger heterogeneous populations such as severe diabetic complications, comorbidities and different *prakriti* individuals may be restricted. Given that the study was conducted in a clinical setting at a single center with only classical preparation of study drug prepared as per the classical Ayurvedic texts, applicability of the study may vary in other regions where the method of preparation of the study formulation as well study population differ. Large multicenter randomized trials are needed in order to determine the external validity.

4.8 Overall Interpretation

In the curent study, *Nisha Triphaladi Yoga* produced marked improvements in both subjective symptoms of *Madhumeha* as well objective hyperglycemia (RBS) in a consistent manner. Observed benefits was considerably large and clinically

meaningful. In addition, there was no adverse events noted suggesting a good benefit-risk profile for the formulation. Present findings are in accordance with previous evidence base of antidiabetic and *Rasayana* action of turmeric and *Triphala*. Though, considering above mentioned limitations of study design, it is prudent to interpret the findings cautiously. Although, it is likely that improvements noted were due to the pharmacological actions of formulation, fact that there was no comparator group in the study, do not allow definite causal inference. In conclusion, the study completes the evidentiary framework supporting the traditional use of *Nisha Triphaladi Yoga* in *Madhumeha*. However, further larger studies of a controlled nature are warranted in order to enhance the evidence base.

4.9 Implications for clinical practice and future research

The results obtained in this study suggest that *Nisha Triphaladi Yoga* has significant role in managing *madhumeha*. Since this *Yoga* produced good relief in *Madhumeha* symptoms and being easy administered can be used in the Ayurvedic management of *Madhumeha*. Further investigations with large clinical trial and randomized controlled designs as well with long duration of follow up including biochemical markers like HbA1c and insulin resistance parameters are needed to establish sustained benefits. Effectiveness should be directly compared with standard treatments, Also the Mechanistic studies of the ingredients must be conducted in future to support the clinical evidences.

5. Conclusion

The current pre and post interventional study highlights the effect of *Nisha Triphaladi Yoga* in *madhumeha* (T2DM), as it showed significant improvement in subjective symptoms of *Apatyanimittaja Madhumeha* as well objective glycemic status (RBS) over a period of 90 days and no adverse events were noted including hyperglycemia. Findings of present investigation indicates that, *Nisha Triphaladi Yoga* is safe, well-tolerated and may be clinically useful in the management of *Madhumeha*, in accordance with classical Ayurvedic description and present-day clinical relevance. Although, the findings must be interpreted in the context of the observed limitations, that is a small sample size, lack of a parallel control arm and limited biochemical assessment. Hence, further future well designed and sufficiently powered randomized controlled trials must be undertaken to substantiate its efficacy and explore long-term outcomes and enhance generalizability of the results. In summary, intervention has a promising therapeutic potential and necessitates an in depth scientific evaluation.

5. Financial support

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6. Author Contribution

RB: Conceptualisation, Software, Formal analysis, Investigation, Resources, Data curation, Writing-original draft, Visualization, Supervision. **DRS**: Interpretation of Data, drawing conclusions from the study, drafting the study. **BP**: Conceptualization, Methodology/study design, Software, Validation, Investigation, Resources, Data curation, Supervision, Writing-review and editing. **BM**: Methodology/study design, Validation, Formal analysis, Investigation, Resources, Data curation, Writing-review and editing.

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8. Conflict of interest

There are no conflicts of interest.

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