



ORIGINAL RESEARCH PAPER

Ayurveda

THE CLINICAL ASSESSMENT OF NISHA AMALAKI YOG IN NON-PROLIFERATIVE DIABETIC RETINOPATHY

KEY WORDS: Non-proliferative diabetic retinopathy, Nisha Amalaki Yog, Ayurveda, microvascular complications, diabetic eye disease.

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ABSTRACT

Background: Diabetic retinopathy (DR) is a progressive microvascular complication of diabetes mellitus (DM) and remains one of the leading causes of preventable blindness worldwide. Non-proliferative diabetic retinopathy (NPDR) is the earliest stage of DR, marked by microaneurysms, retinal hemorrhages, and exudates. Modern management relies primarily on glycemic control and laser photocoagulation, yet these methods have limitations, including cost, accessibility, and side effects. Ayurvedic literature describes Nisha Amalaki Yog as beneficial for Prameha (diabetes) and its ocular complications, with potential antioxidant and microvascular-protective actions. **Aim:** To clinically evaluate the efficacy of Nisha Amalaki Yog in patients with NPDR. **Methods:** Thirty patients with type 2 DM and NPDR were enrolled in a randomized, placebo-controlled study. Participants were divided equally: Group A received Nisha Amalaki Yog (6 g twice daily) for six months; Group B received placebo. Both groups continued standard anti-diabetic therapy. Outcomes assessed included subjective symptoms (floaters, flashes, diminution of vision) and objective retinal changes (microaneurysms, hemorrhages, exudates, venous beading). **Results:** No statistically significant differences were observed between groups in subjective or objective parameters ($p > 0.05$). Microaneurysms were the most common finding, followed by intraretinal hemorrhages (~60%), exudates (37%), and venous changes (17%). The intervention was well tolerated with no adverse effects reported. **Conclusion:** Nisha Amalaki Yog did not show measurable short-term clinical benefit over placebo in NPDR management. However, its safety profile warrants further research in larger, longer-duration studies, ideally incorporating Shodhana (purification) protocols as per Ayurvedic principles.

1. INTRODUCTION

Diabetic retinopathy is a microvascular complication caused by chronic hyperglycemia, leading to progressive retinal capillary damage, ischemia, and, in advanced stages, neovascularization. DR is classified into two major stages: non-proliferative diabetic retinopathy (NPDR) and proliferative diabetic retinopathy (PDR). NPDR is characterized by microaneurysms, dot-and-blot hemorrhages, lipid exudates, and venous abnormalities. Without timely management, NPDR can progress to PDR, which has a high risk of severe vision loss.

Globally, DR affects over 93 million individuals. In India, the prevalence of DM is increasing rapidly, with urban prevalence rates between 12–19% and DR prevalence among diabetics ranging from 18–27%. The socioeconomic burden of DR is high, as it often affects individuals in their working years, leading to both economic and quality-of-life impacts.

From an Ayurvedic perspective, DR correlates with Pramehaj Drishtipatalgata Roga, a complication of Prameha (diabetes). Pathogenesis involves vitiation of Kapha along with Rakta, Mamsa, Meda, and Majja Dhatus, which progressively damages retinal tissues (Drishti Patala). Classical texts mention Nisha Amalaki Yog, a combination of turmeric (*Curcuma longa*) and amla (*Emblica officinalis*), as a potent formulation for Prameha and ocular health. Pharmacological studies have confirmed its antioxidant, anti-glycation, anti-inflammatory, and microvascular-protective properties, suggesting potential utility in early-stage DR.

This study was designed to clinically assess whether Nisha Amalaki Yog could benefit patients with NPDR when used alongside standard diabetic care.

2. MATERIALS AND METHODS

2.1 Study Design

Randomized, placebo-controlled study conducted at Vidarbha Ayurved Mahavidyalaya, Amravati, with ethics approval (MUHS/PG/E-3/42/04/958).

2.2 Participants

Thirty patients with type 2 DM and NPDR were recruited after satisfying inclusion and exclusion criteria and providing informed consent.

Inclusion Criteria

- Type 2 DM with clinically confirmed NPDR (one or both eyes).
- Stable on oral hypoglycemic agents.
- Mentally fit to consent.

Exclusion Criteria

- Proliferative DR.
- Severe systemic illness (malignancy, nephropathy, dialysis).
- Pregnancy.
- Significant ocular media opacities (e.g., dense cataract).

2.3 Randomization and Intervention

Patients were randomized (lottery method) into:

- Group A (Trial): Nisha Amalaki Yog 6 g twice daily for six months.
- Group B (Placebo): Identical-looking placebo capsules for six months.

Both groups continued their prescribed anti-diabetic medications.

2.4 Drug Preparation

Fresh amla fruits and turmeric rhizomes were cleaned, processed via the Bhavana method, shade-dried, powdered, and standardized (curcumin content: 1.02% w/w).

2.5 Outcome Measures

- Subjective: Floaters, flashes, diminution of vision (graded 0–3).
- Objective: Microaneurysms, hemorrhages, exudates, venous beading (graded via 12-sector fundus photography).

2.6 Statistical Analysis

GROUP- A TRIAL Chief complaints	Mean score		Diff	% of diff/Relief	paired 't' test				Remarks
	BT	AT			S.D (BT/AT)	S.E.M (BT/AT)	t	p	

DOV	1.44	1.48	-0.04	-2.77	0.5831/0.6532	0.1166/0.1306	1	0.3773	NS
perception of false flashes of light	0	0	0	0	0	0	0	0	
Floater	0	0	0	0	0	0	0	0	
Microaneurysms	1.72	1.64	0.08	4.65	1.061 /1.114	0.2123/0.2227	0.6247	0.5381	NS
Haemorrhages	1.2	0.96	0.24	2.0	1.384/1.136	0.2769/0.2272	1.186	0.2471	NS
Exudates	0.6	0.64	-0.04	-6.66	1.190/1.221	0.2380/0.2441	1	0.3273	NS
Venous beading	0.12	0.16	-0.04	-33.33	0.3317/0.4726	0.066/0.0945	1	0.3273	NS

GROUP-B PLACEBO Chief complaints	Mean score		Diff	% of diff/Relief	Paired 't' test				Remarks
	BT	AT			S.D.	S.E.M	t	p	
DOV	1.536	1.536	0	0	0.6929/0.7927	0.1310/0.1498	0	1	NS
Perception of flashes	0	0	0	0	0	0	0	0	0
Floater	0	0	0	0	0	0	0	0	0
Microaneurysms	2.429	2.357	0.072	2.964	1.168/1.224	0.2208/0.2313	0.5704	0.5732	NS
Haemorrhages	1.75	1.786	-0.36	-2.05	1.295/1.197	0.2447/0.2263	0.1825	0.8566	NS
Exudates	1	1	0	0	1.36/1.33	0.2272/0.2520	0	1	NS
Venous beading	0.25	0.2857	-0.0357	-14.28	0.4410/0.5345	0.0833/0.1010	1	0.3262	NS

Paired t-test for within-group analysis, unpaired t-test for between-group comparisons; $p < 0.05$ considered significant.

Comparison between two group is essential to decide the efficacy of prepared drug . An unpaired 't' test was run on a sample of 30 patients, randomly divided into two groups; to determine if there were difference in parameters Nisha-AmalakiYog (Trial group) and Placebo group.

Comparison Between Two Group

Comparison between two group				Unpaired 't' test				
Chief Complaints	diff/relief of trial gp	Relief of placebo gp		S	SM	T	p	Remarks
DOV	-2.77	0		0.1826/0.262	.0333/0.0479	0.5708	0.5703	NS
Floater	0	0						
Flase flash of light	0	0						
Microaneurysm	4.65	2.964		0.5833/0.639	0.1065/0.116	0	1	NS
Haemorrhage	2	-2.05		0.9248/0.999	0.1688/0.182	0.9386	0.3518	NS
Exuates	-6.66	0		0.1826/0.262	0.0333/0.0479	0.5708	0.5703	NS
Venous beaing	-33.33	-0.0357		0.1826/0.182	0.333/0.333	0	1	NS

Overall Effect of Therapy in Group A and Group B3. Results

Sr. No.	%Relief	Result	A	%	B	%
1	100	Cured	0	0	0	0
2	75-99	Marked improvement	0	0	0	0
3	51-74	Moderate improvement	1	4	0	0
4	26-50	Mild improvement	1	4	2	7.142
5	<25	Benefited	6	24	8	28.57
6	0	unchanged	13	52	9	32.14
7	Negative	Progression	4	16	9	32.14
			25		28	
			Eyes		Eyes	

3.1 Demographics

Most patients were aged 50–59 years, aligning with the chronic nature of DM and the time needed for microvascular retinal changes to develop.

3.2 Symptom Profile

Floater and flashes were absent in both groups, consistent with NPDR's early stage where vitreous involvement is uncommon. Diminution of vision was present in variable grades.

3.3 Fundus Findings

- Microaneurysms: ~100% of eyes.
- Intraretinal hemorrhages: ~60% of eyes.
- Exudates: 37% of eyes.
- Venous beading: 17% of eyes.

3.4 Statistical Findings

No statistically significant difference between trial and placebo groups in all subjective and objective measures ($p > 0.05$).

4. DISCUSSION

This study did not detect a measurable benefit of Nisha Amalaki Yog over placebo in NPDR within six months. Several

factors may explain this outcome:

1. **Short Duration:** Retinal changes in NPDR progress slowly, and structural improvements may require longer treatment periods.
2. **Absence of Shodhana Therapy:** Ayurvedic theory emphasizes purification before Rasayana to enhance therapeutic efficacy.
3. **Stage of Disease:** Interventions may have more effect in earlier microvascular dysfunction before structural retinal lesions become established.

Modern research on turmeric and amla shows promising biochemical effects in diabetes, including reduction of oxidative stress and inhibition of advanced glycation end-products (AGEs). However, translating these biochemical benefits into measurable retinal improvements may require extended treatment, higher doses, or bioavailability enhancement.

5. CONCLUSION

Nisha Amalaki Yog was well tolerated but did not significantly improve NPDR outcomes over placebo within six months. Its safety profile supports further exploration in:

- Larger, multicenter trials.
- Longer durations (≥ 12 months).
- Combination with Shodhana (panchkarma) therapies.
- Integration with modern imaging (OCT, fluorescein angiography) and biochemical markers.

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