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Review of research work done on *Nishamalaki* in type 2 Diabetes at institute of Teaching and Research in Ayurveda, Jamnagar

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ABSTRACT

Background: *Nisha* and *Amalaki Churna* are most commonly prescribed drugs used individually as well as in combination with other drugs in various diseases by Ayurvedic practitioners. The use of *Nisha* and *Amalaki* in *Prameha* is found in various classical texts, including Brihatrayees, Chakradatta, Bhaishajya Ratnavali among others. Diabetes is a major cause of health concern affecting around 10.5% of population. The most worrisome part is that its incidence is on the rise even in rural areas. *Prameha (Madhumeha)* w.s.r. to Type 2 Diabetes has adverse effects on many physiological processes and anatomical structures in the body (*Saptadushya*) and is considered as *Mahagada*. **Aim:** of the present study was to compile such research works carried out on *Nishamalaki* at ITRA, Jamnagar and provide brief information about the studies. **Material & Methods:** Total nine studies on *Nishamalaki* were screened from various PG departments of Institute of Teaching and Research in Ayurveda, Jamnagar. **Results and Conclusion:** All studies revealed that *Nishamalaki* reduces the clinical symptoms of Diabetes. The clinical efficacy has been evaluated in both type 1 (in modified form) and type 2 Diabetes. Satisfactory response with a decrease in the intensity of signs and symptoms was reported in all the studies. No adverse effects were reported in any of these studies.

Key words: Diabetes, Madhumeha, Nishamalaki, Prameha, Type 2 Diabetes

INTRODUCTION

Nisha and *Amalaki Churna* are widely popular drugs used individually and together in various diseases by Ayurvedic practitioners. The use of *Nisha (Curcuma longa* Linn.) and *Amalaki (Emblica officinalis* Gaertn.) in

Prameha is found in various classical texts, including Brihatrayees^[1-4], Chakradatta^[5], Bhaishajya Ratnavali^[6] among others. Specifically, the use of *Amalaki Swarasa* with *Haridra Churna* is widely popular in *Prameha*^[7] (Type II Diabetes).

Diabetes is a major cause of health concern affecting around 10.5% of population.^[8] The most worrisome part is that its incidence is on the rise even in rural areas. *Prameha (Madhumeha* w.s.r. to Type II Diabetes Mellitus) has adverse effects on many physiological processes and anatomical structures in the body (*Dashadushya*)^[9] and is considered as *Mahagada*^[10]. *Madhumeha* is mentioned as *Chirakari Vyadhi*^[11], with involvement of 10 *Dushyabhava*.^[9] Diabetes is an important cause of blindness, kidney failure, lower limb amputation and other long-term consequences that impact significantly on quality of life. Though there are various drugs mentioned in modern medicine for

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the symptomatic relief, the chances of their adverse drug reactions are very high. Hence, considering the utility of *Nishamalaki* in disease diabetes many research works have been carried out at Institute of Teaching and Research in Ayurveda (ITRA), Jamnagar with an intention to revalidate the classical principles of therapeutics. The present study was to compile all available research works done at ITRA.

MATERIALS AND METHODS

Works carried out at the different departments of ITRA, Jamnagar at PhD and PG levels during 1960-2023 were compiled and screened to revalidate the classical concepts of Diabetes management.

OBSERVATIONS AND RESULTS

Initial studies carried out in 1979^[12] evaluated the effect of two drugs administered simultaneously, that is *Amalaki Rasayana* and *Haridra Churna* (not pharmaceutically processed) in the management of type 2 diabetes in 14 patients. *Amalaki Rasayana* was administered in the dose of 8g/day in four divided doses, while *Haridra Churna* was administered in the dose of 16g/day in four divided doses, both for a period of 60 days. Blood sugar levels of the patients was tested after every 15 days. Statistically significant reduction ($p < 0.01$) at 45th and 60th day was found. Additionally, with more duration of administration there was subsequent reduction in Fasting Blood Sugar (FBS) during Glucose Tolerance Test (GTT) at all tested intervals. The study also evaluated long term effect of administering the two drugs in healthy individuals.

Another study was carried out in 1982^[13], wherein 4 g of *Haridra Amalaki Ghanavati* was administered twice a day in 100 patients of type 2 diabetes, for a duration of 45 days. There was insignificant reduction in Blood Sugar Level (BSL) during GTT after treatment. However, clinically, reduction in signs and symptoms of DM-II was observed.

A study was conducted in 1984^[14] where in *Devadarvyadi Ghanavati* (Control Group) was prepared with method of preparation of *Ghana* and *Devadravyadi Haridra Amalaki Churna* (Trial drug) was prepared by taking powders of raw ingredients of

Devadarvyadi Ghanavati and significantly more quantity of combined *Churna* of *Haridra* and *Amalaki*. The study was conducted for 1 month in the patients of type 2 diabetes. Both the drugs were administered in the dose of 3g/day. The trial drug was administered in 13 patients while the control group had 9 patients. The trial drug showed significant ($P < 0.05$) reduction in FBS against insignificant reduction ($p > 0.1$) in control group.

Further studies were conducted in 2015^[15] among 27 patients of type 2 Diabetes. *Haridra Amalaki Churna* (*Churna* in proportion 1:2) was administered in the dose of 6g twice a day for 6 weeks. It showed insignificant reduction in FBS and Postprandial blood sugar (PPBS) but significant reduction in clinical signs and symptoms.

A study conducted in 2017^[16] evaluated the role of drug combination and effect of *Nisha*, *Amalaki* and *Nisha Amalaki Yoga* on glucose metabolism and their antidiabetic effect. *Nisha Churna* (NC) and *Amalaki Swarasa Bhavita Amalaki Churna* (ASBAC) compounded into combination formulation *Amalaki Swarasa Bhavita Nishamalaki Churna* (ASBNAC) preserved Tannin content as well as prevented degradation of NC. Difference in leachability of *Amalaki Churna* and *Amalaki Swarasa Bhavita Amalaki Churna* suggested significant difference of *Amalaki Swarasa* from *Churna* and impact of *Bhavana*. ASBAC possessed better alpha amylase and alpha glucosidase inhibitory activity in in-vitro study than ASBNAC and NC at all tested concentrations.

Another study was conducted in 2018^[17] wherein 60 patients of type 2 diabetes were administered with *Nishamalaki Yoga* for 8 weeks. 2 tablets of 500mg were administered twice a day after meals. Results were assessed on the basis of chief complaints, FBS, PPBS, HbA1c, waist to hip ratio and BMI. The trial drug showed statistically significant decrease in FBS, PPBS and HbA1c levels.

A study on Juvenile diabetes (*Jataja Prameha*) conducted in 2023^[18] evaluated the effect of modified *Nishamalaki Yoga* in patients of *Jataja Prameha*. Here, the trial drug was prepared by triturating *Haridra*

Churna (powder form) with *Amalaki* and *Guduchi* (*Tinospora cordifolia* Willd.) *Kashaya* (decoction). 12 patients were given the trial drug for a period of 3 months. It was compared with a control group of 7 patients wherein, no active Ayurvedic intervention was done on the patients; their conventional medications were continued and were observed on a weekly basis. The trial group showed statistically significant difference in chief complaints, FBS and PPBS values.

Another study with the same modified *Nishamalaki Yoga* was conducted to evaluate its anti-hyperglycemic effect in glucose overloaded Swiss albino mice.^[19] The mice were divided into three groups. First was a control group, second was treated with modified *Nishamalaki Yoga* and the third was given standard treatment. After 1h of drug administration, glucose (5g/kg, po) solution in distilled water was administered to all groups orally to induce hyperglycemia. Thereafter, BSL was recorded at 30min, 60min, 90min and 120min of post glucose overload for assessing the anti-hyperglycemic activity of the test drug. The modified *Nishamalaki Yoga* treated group produced more anti-hyperglycemic activity at some extent followed by standard treated in glucose overloaded hyperglycemic mice at 120min.

Another study was conducted in 2022^[20] to compare the clinical efficacy of two trial drugs, i.e. *Kantkateryadi Vati* and *Nishamalaki Vati* in 40 patients of *Madhumeha* (type 2 diabetes) that were randomized into two groups. The group that was administered with *Kantkateryadi Vati* showed better results than that administered with *Nishamalaki Vati*. The study duration was of 8 weeks with a follow up period of 4 weeks. The dose of both the drugs was 500mg two times a day after meals.

Recent study conducted on Juvenile Diabetes in 2023^[21] included 20 patients randomized into two groups. One received *Guduchyadi Yoga - Guduchi, Amalaki* and *Haridra Churna* triturated with *Kashaya* of *Guduchi, Amalaki* and *Haridra*. The other received modified *Nishamalaki Yoga - Guduchi* and *Amalaki Kashaya Bhavita Haridra Churna*, both for a period of 8 weeks. Follow up was taken after one month. The group administered with *Guduchyadi Yoga* showed

better results than the one administered with modified *Nishamalaki Yoga*.

DISCUSSION

Out of the 9 previous reviewed theses, 8 were clinical while one was animal experimental and in vitro study. Out of the two studies on Juvenile diabetes, one was an animal experimental and clinical study carried out as a PhD dissertation, while the PG dissertation was a clinical study. The minimum dose in clinical studies was observed to be 500mg while the maximum dose administered is 6g. average duration of the clinical studies was 8 weeks. Although the formulation *Nishamalaki* (in modified form or unmodified form) has not always resulted in statistically significant reduction in blood sugar levels, but in almost all the studies, it has produced statistically significant relief in the signs and symptoms of Diabetes. Thus, the previous reviewed theses on *Nishamalaki* in the management of Diabetes has shown significant results.

The study of 1979^[12] wherein 14 diabetic patients were treated with *Haridra* and *Amalaki Rasayana*, both *Medadushti* and *Kledadushti* was observed. Apart from these, the drugs were also administered in 10 healthy volunteers and 16 non-diabetic patients having other diseases. The use of *Haridra* in non-diabetic patients showed mild hypoglycemic effect which passed off shortly. The author is of the opinion that there is no harm, especially in terms of hypoglycemia, in using *Haridra* as condiment; moreover, it may perhaps prevent the development of *Prameha*.

In the study of 1982^[13], 100 patients were observed, most of which, were *Apathya Nimittaja*. The author concluded that it was less advantageous to depend merely on the trial drugs for hypoglycemic effect but the drugs may provide a good adjunct for reducing the dose of proved hypoglycemic agents and also provide chemical relief to the patients.

The study of 1984^[14] observed that good response was achieved on the biochemical parameters on increasing the dose of *Devadarvyadi* and *Haridramalaki Churna*. It was also observed that the trial drugs were more effective in those patients who had taken only

Ayurvedic treatment and no other hypoglycemic drugs. In the 5-insulin dependent diabetic patients, a gradual reduction in the dosage of insulin was found on administering the trial drugs.

The 2015 study on *Pratyaksha Pareeksha* in Ayurveda and its applied utility in *Prabhutavila Mutrata* in patients of *Madhumeha*^[15] showed 56.50% relief in FBS values, while the PPBS levels showed 12.95% relief. It showed statistically significant result in *Prabhuta Mutrata* and statistically insignificant results in *Avila Mutrata*.

The 2017 study^[16] on the role of drug combinations showed antidiabetic effect along with protective effect on Liver and Kidney and in view of dyslipidemia; a risk factor for ischemic heart disease, Atherosclerotic diseases and systemic arterial hypertension in diabetics. As all the test drugs had shown Alpha amylase and Alpha Glucosidase inhibitory activity, hence it was concluded that the test drugs NC, ASBAC and ASBNAC are useful in control of postprandial hyperglycaemia. Comparatively better reversal of hyperlipidaemia was seen by ASBNAC suggesting *Medohara*, *Rukshana*, *Lekhana* and *Karshana* properties of *Nisha* and *Amalaki* mentioned in classical Ayurvedic texts and Pharmacopoeia.

The study conducted in 2018^[17] on the management of *Madhumeha* (Type 2 Diabetes) by *Amalaki Bhavita Nisha* in *Vati* form showed marked difference in pharmacognostical and phytochemical characters of *Nisha* before and after *Bhavana*. Most of the cellular constituents i.e. oleoresin, oil globule disturbed parenchyma cells were freely distributed due to the *Bhavana* process. The study showed that, in FBS after 4 weeks 10.85% relief and after 8 weeks 9.29% relief was found. In PPBS after 4 weeks 9.38% relief and after 8 weeks 7.34 % relief was found.

The 2023 study on juvenile diabetes^[18] was conducted on 21 patients aged between 2years-16years. As children with Juvenile diabetes must take insulin as a part of their treatment, the study observed 20 out of 21 of its subjects having a positive history of taking injectable insulin. Improvement in the complaints of *Karapadataala Daha* and *Suptata* was found due to the

neuroprotective effect of *Amalaki*^[22], *Haridra*^[23] and *Guduchi*.^[24] In reducing the dose of injectable insulin, insignificant difference was found after one month of treatment, while significant difference was found after two and three months of treatment and also at the end of follow up period.

In the study performed in 2023 on patients of *Jataja Prameha*, improvement was seen in FBS, PPBS, HbA1c and C-peptide in both the groups (receiving *Guduchyadi Yoga* and Modified *Nishamalaki Yoga*) suggesting the reduction in oxidative stress related to hyperglycemia. The author attributed this reduction to the multifactorial effect of the ingredients demonstrating *Pramehaghna* property of *Guduchi* and *Haridra*^[25] and *Rasayana* property of *Amalaki*, *Haridra* and *Guduchi*.^[26]

Type 2 Diabetes was first described as a component of metabolic syndrome in 1988.^[27] Type 2 DM is characterized by insulin insensitivity as a result of insulin resistance, declining insulin production, and eventual pancreatic beta-cell failure.^[28,29] This leads to a decrease in glucose transport into the liver, muscle cells, and fat cells. There is an increase in the breakdown of fat with hyperglycaemia. The involvement of impaired alpha-cell function has recently been recognized in the pathophysiology of type 2 DM.^[30]

Gallic acid from *Amalaki* is proven to improve insulin sensitivity by upregulation of pAkt, PPAR- γ and Glut4.^[31] In vitro studies examining the effects of curcumin from *Haridra* indicate increased glucose uptake and utilization by skeletal muscle cells and adipocytes, and inhibition of gluconeogenesis.^[32] Turmeric and curcumin supplementation reduce oxidative stress encountered by the diabetic rats, by the decreased influx of glucose in to the polyol pathway leading to an increased NADPH/NADP ratio and elevated activity of the potent antioxidant enzyme GPx.^[33] Pancreatic beta cell function is improved with curcumin treatment with consequent insulin secretion thus alleviating even insulin resistance.^[34] *Nishamalaki Yoga* increases peripheral glucose utilization and decreases hepatic glucose synthesis and/ or increase in

insulin secretion,^[35] due to which a reduction in blood sugar level may be achieved. Protective effect of *Nishamalaki* is seen because of the synergistic combination of *Curcuma Longa* and *Emblica officinalis* contributing through various mechanisms like- increasing insulin sensitivity, increasing glucose uptake, decreasing α glucosidase activity, decreasing amylase activity, increasing insulin release, and decreasing oxidative stress,^[36] thus it also helps in the prevention and management of diabetes complications.

CONCLUSION

A comprehensive review of doctoral and post-doctoral dissertations conducted at the Institute of Teaching and Research in Ayurveda, Jamnagar, has identified *Nishamalaki* as a promising Ayurvedic formulation for the management of *Madhumeha* (Type 2 Diabetes). A total of nine research studies, employing diverse treatment protocols, have been undertaken to investigate the therapeutic efficacy of *Nishamalaki*. This review serves as a valuable resource for both research scientists and the Ayurvedic community, providing a concise overview of the existing scientific evidence supporting the use of *Nishamalaki* in the treatment of diabetes.

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