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CLINICAL EFFICACY OF VAMANA KARMA FOLLOWED BY NISHAAMALAKI YOGA IN STHULA PRAMEHI W.S.R. TO TYPE-II DIABETES MELLITUS.

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ABSTRACT

Diabetes mellitus is a chronic metabolic disorder prevalent all over the world. *Vamana* is the *Shodhana* procedure which is specific for the elimination of vitiated *Kapha Dosha* to maintain the equilibrium of *Dosha* in body. Thus in the present study, *Vamana Karma* has been selected prior to the administration of *Shamana* drug. After *Samsarjana Krama*, *Nisha-Amalaki* was used as a *Shamana* drug at a dose of 2 gm thrice a day before meals with water for 30 days. Total 15 patients were registered for the present study in which 13 patients completed the treatment and 2 were dropouts. The efficacy of therapy was assessed on parameters like relief in cardinal signs and symptoms,

blood sugar level, lipid profile and other biochemical parameters. After evaluating the total effect of therapy, it was observed that the therapy provided highly significant relief in cardinal signs and symptoms and significant reduction in blood sugar level.

KEYWORDS: *Sthula Pramehi*, Type-II Diabetes mellitus, *Vamana*, *Nisha-Amalaki*.

INTRODUCTION

Diabetes mellitus is defined as a Disturbance of intermediary metabolism, manifesting as a chronic sustained hyperglycemia primarily due to absolute or relative lack of insulin or either.^[1]

As per recent WHO assessment, there are 171 million people are reported to be suffering from this disease and expected prevalence will be 366 million at the end of 2030.^[2] According to the International Diabetes Foundation,^[3] India has more diabetics than any other country in the world, although more recent data suggest that China has even more.^[4]The disease affects more than 50 million Indians and kills about 1 million Indians a year.^[5] The average age on onset is 42.5 years.^[6] The high incidence is attributed to a combination of genetic susceptibility plus adoption of a high-calorie Diet, Low-activity lifestyle by India's growing middle class.^[7] The syndrome of Diabetes mellitus (DM) is largely covered under the broad heading of *Prameha*.

However Sthula Pramehi (by Charaka), Apatyanimittaja Prameha (by Sushruta) and Avaranjanya Madhumeha (by Vagbhatta) described in Ayurvedic literature have similarity with Type-II Diabetes mellitus. The factors which provoke Kapha & Pitta Dosha cause Santarpanjanya Prameha. In this type of Prameha, Kapha is the predominant Dosha while the important Dushyas are Meda and Kleda. In Avaranjanya Prameha Samprapti, vitiated Kapha & Pitta obstruct the path of Vata, causing its provocation. Samshodhana is the best treatment for elimination of Doshas. Vagbhatta has mentioned that Doshas should be eliminated through the nearest passage. [8] So in the present study Vamana has been selected.

Nisha-Amalaki Yoga has been selected for Shamana therapy after Samsarjana Krama as mentioned in Charaka Samhita, Prameha Chikitsa Adhyaya. [9] This formulation contains Nisha and Amalaki both are having hypoglycemic and hypolipidemic action. [10]

AIMS AND OBJECTIVES

To assess the effect of *Vamana Karma* followed by *Nisha-Amalaki Yoga* in *Sthula Pramehi* (Type-II Diabetes mellitus).

MATERIALS AND METHODS

Total 13 patients of classical sign and symptoms of *Sthula Pramehi* (Type-II Diabetes mellitus) attending the O.P.D. or I.P.D. of Department of *Panchakarma* of I.P.G.T and R.A., G.A.U., Jamnagar were selected for the study irrespective of their sex, caste etc. taking into consideration the inclusion and exclusion criteria.

Inclusion criteria

- Patients of NIDDM with blood sugar level; FBS- 126 to 170 mg/dl or PPBS-150 to 300 mg/dl.
- 2) Age group of 20-60 years.
- 3) Patients of *Prameha* having BMI >25 35.
- 4) Patient otherwise healthy and fit for *Vamana Karma* as per the *Ayurvedic* classics.

Exclusion criteria

- 1) Age < 20 yrs and > 60 yrs
- 2) Patients of *Prameha* having BMI < 25 & >35 and Disease Chronicity > 10yrs.
- 3) Patients of Type-1 Diabetes or the patients of Type-2 Diabetes taking Insulin.
- 4) Patients having complications of Diabetes like Nephropathy, Retinopathy, Diabetic Foot, Carbuncles etc.
- 5) Patients not fit for Vamana Karma as per the Ayurvedic classics.

6) Laboratory investigation

Following investigations were carried out in all the patients.

- Routine Hematological Examinations like Hb%, TLC, DLC, ESR were done to rule out any other pathological condition.
- Biochemical Examinations like Blood Sugar level: Fasting and post-Prandial.
- Lipid profile: S. Cholesterol, S. Triglyceride, S. HDL, LDL, VLDL
- Blood urea and S. Creatinine
- Urine: Routine and Microscopic Examination

Ethical approval

The research protocol was approved by the institutional ethics committee, I.P.G.T. and R.A., Jamnagar.

Treatment protocol

Procedure	Drug, Dose	Duration
Deepana-Pachana	Trikatu Churna-3gms TID (with hot water)	3-5 days
Snehapana	Triphala Taila	3-7 days (As per Kostha & Agni)
Abhayanga and Svedana	Bala Taila & Bashapa Sveda BD	1 day
Vamana	Ikshwaku Churna 3-5 gms, Vacha-2gms, Saindhava -1gms, Madhu-q.s.	1 day
Samsarjana Krama	Peyadi	3-7 days (As per <i>Shuddhi</i>)
Shamana (After completion of Samsarjana Krama)	Nisha-Amalaki Churna 2gms tid with water	30 days

Criteria for assessment of overall effect of therapy

The overall effect was assessed on the basis of relief in chief and associated complaints, decrease in fasting blood sugar & post prandial blood sugar and decrease in S.cholesterol, S.triglyceride.

Overall effect of therapy was assessed on the basis of following criteria:

Controlled: 100% improvement

Marked improvement: ≥ 75% improvement

Moderate improvement: ≥ 50-74% improvement

Mild improvement: $\geq 25-49\%$ improvement

No improvement: <25% improvement

Statistical analysis

The wilcoxon signed rank method^[11] was used to check the significance of the subjective criteria and paired 't' test^[12] was used for objective criteria.

The obtained results were interpreted as follows:

P>0.05, insignificant improvement

P<0.05, Significant improvement

P<0.001, highly significant improvement

Follow up: After completion of treatment Patients were advised to visit hospital once in fortnight for one month.

OBSERVATIONS AND RESULTS

1) General observations

A majority of the patients in this study i.e.53.33% belonged to the age group of 51-60 years, 53.33% were female, all patients were married, 73.33% patients of this series were vegetarians and 60% were addicted to tea or coffee. 66.67% confirmed the family history positive and maximum Chronicity was 3-6 years. 46.67% were having *Kapha-Vataja Prakriti*. All patients had BMI between 25 to 35 and 73% were having *Madhyama Jarana Shakti* and 53.33% patients were having *Madhyama Koshtha*.

Among the chief complaints of *Prameha* all patients having *Prabhuta Mutrata* (polyurea) (100%), maximum numbers of patients were having *Avila Mutrata* (turbid urine) (73.33%), *Kshudhadhikya* (increase in appetite) (53.33%), *Trishnadhikya* (polydypsia) (46.67%) and

Pindikodweshtana (leg cramps) (20%). Also, among associated signs and symptoms of *Prameha* maximum numbers of patients were having *Daurbalya* (weakness) (53.33%), *Atisweda* (excessive sweating) (40%), *Galatalu Shosha* (dryness in mouth) (33.33%), *Karapadatala Daha* (burning sensation in palm and feet) (26.67%) *Karapadatala Suptata* (numbness in palm and feet) (20%), and Klaibya (loss of libido) (20%).

Table 1: Complaints observed in 15 patients of *Prameha*

Chief complaints	No. of pt.	(%)	Associated complaints	No. of pt.	(%)
Prabhuta Mutrata	15	100	Karapadatala Daha	4	26.67
Avila Mutrata	11	73.33	Karapadatala Supatata	3	20
Kshudhadhikya	8	53.33	Atisweda	6	40
Trishnadhikya	7	46.67	Gala-Talu Shosha	5	33.33
Pindikodweshtana	3	20	Daurabalya	8	53.33

Days required for Samyak Snehana: Among 15 patients of *Prameha* 33.33% of the patients obtained *Samyaka Snigdha Lakshana* on 5th day.

Total quantity of *Sneha*: Maximum 60% of the patients required total quantity between 600-800 ml.

Maximum given dose on last day: 40% of the patients were given max. dose on last day between 200-250 ml.

Samyak Snigdha Lakshana: Agnidipti (accelerated digestive power) and Adhastad Sneha Darshana (Visible fats in stool) was observed in all the patients, Snehodvega (intolerance to fat) was observed in 86.67% of the patients, Vatanulomana (Passage of flatus) was noticed in 60% of the patients, Klama (Neurasthenia) was complained by 53.33% of the patients, Glani (Lethargy) was observed in 46.67% of the patients, Tvak Snigdhata (Oleos skin) was noted in 53.33% of the patients.

Table 2: Samyaka Snigdha Lakshana observed in 15 patients of Prameha

Samyaka Snigdha Lakshana	No. of pt.	(%)	Samyaka Snigdha Lakshana	No. of pt.	(%)
Agnidipti	15	100	Adhastad Sneha Darshana	15	100
Snehodvega	13	86.67	Glani	7	46.67
Tvaksnigdhata	8	53.33	Klama	8	53.33
Vatanulomana	9	60			

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Samyak Swinna Lakshana: All the patients reported Samyak Swinna Lakshana like Shita Shamana (Disapperance of cold), Stambha Nigraha (relief from stiffness), Gaurav Nigraha (relief from heaviness), Laghuta (lightness in the body) and Sveda Pradurbhava (Sweating).

Vamana Karma observation

Average Quantity taken for *Akanthapana* was 1.11 lit., Average dose of *Ikshwaku* was 4.46gm. Average quantity of *Yashtimadhu Phanta* ingested was 4.25lit. Average quantity of *Saindhavajala* taken was 2.83 lit. Difference of average quantity of output and input was 0.36 ml. Time taken for induction of first *Vega* was 28min (Avg.), Average number of *Vega* was 7.06 and Average number of *Upavega* was 7.62.

Quality of Vamana Vega

After giving *Vamaka Yoga*, Self induced *Vega* was observed in 76.92% of patients and Projectile *Vega* was observed in 84.61% of patients, with the Support of *Vamanopaga Dravya* in 23.07% of patients.

Pittanta Vega was observed in Vamana

In Vamita Dravya Clear Pitta was appeared in the end in 76.92% of the patients.

Samyaka Vamana Lakshana

In each of 92.3% of the patients *Kale Pravriti* (Self induction) *Yathakrama Doshaharnama* (elimination of *Doshas* in order of *Kapha*, *Pitta*, *Vata*) and *Kantha Shuddhi* were observed, All the patients had *Hridaya Shuddhi*, *Parshva Shuddhi*, *Murdha Shuddhi* and *Sharira Laghava* (Lightness in the body). *Agni Vriddhi* (Increased digestive power) was observed in 76.92% of the patients, *Anatimahati Vyatha* (without pain) was found in 69.30% of the patients. 92.30% of the patients were complained *Daurbalya* (weakness).

Table 3- Samyaka Vamana Lakshana observed in 13 patients of Prameha

Samyak Vamana Lakshana	No. of pt.	%	Samyak Vamana Lakshana	No. of pt.	%
Kale Pravriti	12	92.30%	Sharira Laghava	13	100%
Yathakrama Doshaharnama	12	92.30%	Daurbalya	12	92.30%
Hridaya Shuddhi	13	100%	Kantha Shudhi	13	100%
Parshva Shuddhi	13	100%	Agni Vridhi	10	76.92%
Murdha Shuddhi	13	100%	Antimahati Vyatha	9	69.23%

Vamana Atiyoga Lakshana- Each of 23.07% of the patients complained of Vata Prakopa (Aggravation of Vata) and Bala Hani (Weakness), 15.38% of the patients were having Daha (Burning), Rakta Chandrika (With blood) was found in 7.69% of the patients. Each of 7.69% of the patients were observed Moha (confusion), Tamah Pravesh (clouding of vision) and Bhrama (confusion).

Complication of Vamana Karma: After completion of the Vamana procedure 15.38% of the patients were having complain of pain in abdomen.

Nature of *Shuddhi* :- Maximum in 53.85% of the patients *Pravara Shuddhi* was achieved; in 46.15 % of the patients *Madhyama Shuddhi* was achieved.

Effect of therapy

Effect of therapy on complaints

It provided Statistically highly significant (P<0.001) relief in *Prabhuta Mutrata* (polyurea) by 89.73%, in *Avila Mutrata* (Turbid urine) by 92.59%, in *Kshudhadhikya* (Polyphagia) by 66.67% and in *Daurbalya* (weakness) by 79.96%, whereas the relief obtained in *Galatalu Shosha* (Dryness in mouth) and *Karapadatala Suptata* (numbness in palm & foot) was 90.90% & 88.89% respectively which was statistically significant (P<0.01). Relief of 83.33% was observed in *Trishnadhikya* (Polydypsia),75.01% in *Pindikodweshtana* (Leg cramps), 77.8% in *Karapadatala Daha* (Burning sensation in palm & foot), 70% in *Atisweda* (excessive sweating) and 83.33% in *Klaibya* (loss of libido) which was statistically insignificant (P>0.05).

Table 4:	Effect	of t	herapy	on	comp	laints
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No	No. Chief complaints		N	Iean	0/ of imn	S.D	S.E	P
110.	Cinei compiants	N	BT	AT1	% of imp.	S.D	5. E	r
1	Prabhuta Mutrata	13	2.143	0.1538	89.73	0.4935	0.1369	0.0002**
2	Avila Mutrata	8	1.200	0.1111	92.59	0.6009	0.2003	0.0078**
3	Kshudhadikya	4	1.200	0.4000	66.66	0.5417	0.4472	0.1250**
4	Trishanadhika	4	1.200	0.2000	83.33	0.7071	0.3162	0.1250
5	Pindikodweshtana	2	1.333	0.3333	75.01	1.000	0.5774	0.5000
6	Karpadatala Daha	4	1.500	0.3333	77.8	0.9832	0.4014	0.1250
7	Karpadatala Supatata	6	1.000	0.1111	88.89	0.7817	0.2606	0.0313*
8	Atisweda	5	1.667	0.5000	70.00	0.7528	0.3073	0.0625
9	Galatalu Shosha	7	1.375	0.1250	90.90	0.7071	0.2500	0.156*
10	Daurbalya	9	1.667	0.3333	79.96	0.5000	0.1667	0.0039**
11	Klaibya	4	1.500	0.2500	83.33	0.5000	0.2500	0.1259

^{* =} P<0.01 (statistically significant), ** = P<0.001(statistically highly significant).

Effect of therapy on body mass index

It provided 2.85% reduction in BMI which was statistically highly significant (p<0.001).

Table 5: Effect of therapy on body mass index

No.		N	Mean		% of	S D	S.E	D
110.		11	BT	AT1	imp.	5. D	S.E	r
1	BMI	13	28.67	27.8	2.85	0.47	0.12	< 0.001

Effect of therapy on biochemical values

It provided statistically significant reduction (p<0.01) in Fasting blood sugar level by 15.8% relief and in Postprandial blood sugar with 26.1% relief. It provided insignificant (p>0.05) reduction in S. cholesterol by 3.6%. While S.HDL and S. triglycerides increased by 5.9% & 3.4% relief respectively which was statistically insignificant (p>0.05). There was decrease in B. urea and S. Creatinine by 2.9% & 3.7% respectively which was statistically insignificant (p>0.05). And urine sugar reduced by 87.5% which was statistically insignificant (p>0.05).

Table 6: Effect of therapy on biochemical values

Biochemical	Mean	values	Mean	%			
values(mg/dl) (n-13)	ВТ	AT2	D.F.	change	S.D.	S.E.	't'
Blood sugar	D1	A12	D.F.	change			
Fasting	145.3	125.9	23	15.8	20.2	5.6	4.10*
Postpranidial	213	157.3	55.7	26.1	63.8	17.2	3.14*
S.Cholesterol	183.4	176.6	6.7	3.6	43.8	11.9	0.57
S.Triglycerides	180.3	186.6	-6.2	-3.4	35.2	9.7	-0.63
S.HDL	44.2	46.8	-2.6	-5.9	5.1	1.4	-1.83
S. cretinine	1.03	1	0.03	3.7	0.19	0.05	0.71
B. urea	28.62	27.4	0.8	2.9	7.9	2.1	0.38
Urine sugar	0.62	0.07	0.54	87.5	1.2	0.33	1.62

Total effect of therapy

None of the patient found complete relief or marked improvement. Moderate improvement was found in 76.92% of patients, while Mild improvement was found in 23.07% of patients, none of the patient remains unchanged.

Table 7: Total effect of therapy

Result	No. of patient	Percentage (%)
Complete remission	0	0
Marked improvement	0	0
Moderate improvement	10	76.92
Mild Improvement	3	23.07
No relief	0	0

DISCUSSION

Discussion on general observation

Majority of the patients belongs to Age group of 51-60 years. These findings were concordant with the recent statistical data, which shows that the onset of type-II DM after the 40s is most common. Majority of the patients were living in urban areas this data is concordant with the WHO annual report that is the prevalence of DM is greater in the urban area than in rural area. [13] 66.67% of the patients confirmed a family history of *Prameha* which shows that genetic predisposition is more important in type-II DM.

Majority patients were afflicted towards *Madhura Rasatamaka*, *Guru-Snigdha Gunatamaka Ahara Sevana* which is said to be *Kapha Prakopaka*, and were having wrong diet pattern like *Adhyashana* and *Vishamashana* which causes metabolic derangement. Also modern science accept the role of diet in diabetes mellitus Sweet foods rich in refined carbohydrate if consumed frequently may increase for insulin secretion, while high fatty foods may increase FFAs and exacerbate insulin resistance.^[14]

Avyayama (lack of exercise), Diwaswapna and Asyasukha (sedentary lifestyle) were found in maximum number of patients which are major factor of Medovaha Srotodushti and Kapha Prakopaka causing insulin resistance or decreasing insulin sensitivity. Lack of exercise, sedentary lifestyle and physical inactivity are causative factors for Type-II Diabetes mellitus.^[15]

Majority of the patients having complaints like *Prabhuta Mutrata*, *Trishnadhikya* and *Kshudhadhikya* in chief complaints and *Daurbalya*, *Atisweda* and *Karapadatala Supatata* in associated complaints. These observations are as per the classics and are also as per the modern science. Few patients were asymptomatic and did not suffer from any chief complaints and were diagnosed on routine investigation procedures.

Discussion on effect of therapies

Prabhuta Mutrata

As *Vamana* expel excessive *Kleda* and *Nisha-Amalaki* yoga has *Kapha*, *Meda*, *Kledahara* and *Mutrasanghrahani* properties as due to that *Prabhuta Mutrata* may be relived.

Avila Mutrata

Avila Mutrata is the outcome of deranged metabolism. Vamana eliminates the morbid matter from the body and thereby makes Srotoshuddhi and improves metabolism so it is relived by either of trial procedures.

Kshudhadhikya

A *Vamana* therapy eliminates the Excessive *Kapha* and *Pitta Dosha* & thus removes *Avarana* of *Vata* there by normalizing the digestive power which helps to control this symptom.

Pindikodweshtana

This complaint was found in many diabetic patients because of less glucose uptake by muscle tissue for energy due to an insulin antagonist effect. [16] *Nisha-Amalaki Yoga* increases peripheral glucose utilization, decreased hepatic glucose synthesis. (Tank R et al, 1989)^[17] hence might be providing relief in *Pindikodweshtana*.

Karapadatala Daha

The relief in *Karapadatala Daha* may be due to *Raktaprasadan Karma*^[18] and *Neuroprotective*^[19] effect of *Nisha* (*Haridra*) provided the relief in this symptom.

Daurbalya

In *Prameha* the symptom *Daurbalya* can be manifested in two ways, firstly as a sign of *Prameha* where it manifests because of disturbed Agni which does not let the body to get proper nourishment. Secondarily as an *Updrava* in chronic cases where it is due to *Dhatukshaya*. *Vamana* by improving *Agni* in long-term & sets up proper metabolism which helps to form *Samyak Dhatu*. Along with *Rasayana* & Antioxidant^[20] properties of *Nisha-Amalaki Yoga* prevents the further *Dhatukshaya*.

Body mass index

The therapy provided 2.85% decrease in BMI at statistically highly significant level (P<0.001). It can be said that Dietary restrictions during *Snehapana*, *Shodhana* and *Samsajana Krama* helps or brings about mobilization of fat from its deposits and *Nisha-Amalaki Yoga* due to its *Laghu Ruksha Guna*, *Tikta*, *Kashaya Rasa*, *Kaphagana* properties and hypolipidemic action^[21] may have provided this effect.

Effect on Biochemical & hematological Values

Fasting & Postprandial Blood Sugar: The therapy provided 15.8% relief in Fasting BSL may be due to *Vamana* procedure. *Vamana* by its mechanism eliminate vitiated *Doshas* and correct *Srotodushti*, purify *Koshta* and improves *Agni Bala*. By this way it acts on microcellular level and help to maintain normal physiology of the tissue which is hampered in the disease process of *Prameha*. It makes the substratum suitable for the maximum drug absorption which in turn increases the bioavailability of *Shamana Yoga*. Also *Nisha Amalaki Yoga* increases peripheral glucose utilization and decreases hepatic glucose synthesis and/or increase in insulin secretion^[22] due to this reduced blood sugar level may be achieved.

Lipid Profile

The therapy provided 3.6% reduction in S. cholesterol, 2.8% reduction in S. triglycerides and 5.9% rise in S.HDL. Restriction of diet during *Snehapana*, *Vamana* and *Samsarjana Krama* helps to brings about mobilization of fat from its deposits. And may be due to *Ruksha*, *Laghu Guna*, *Tikta*, *Katu*, *Kashaya Rasa*, *Katu Vipaka*, *Kaphaghna* and *Lekhaniya* properties of the *Nisha-Amalaki Yoga* might have acted on *Kapha* and *Meda Dhatu*.

According to modern science, an experimental and clinical study postulates that *Nisha-Amalaki* possesses hypocholesterolemic effect which might be helpful in lowering S. cholesterol in present study (Kim et al., 2005;^[23] Thakur et al., 1988;^[24] Mathur et al., 1996;^[25] Mishra et al., 1981^[26]).

Probable mode of action of Vamana Karma in the management of Prameha.

Samshodhana has been given more importance in our classics, as it gives long standing effect. In *Prameha Samshodhana* is advised especially for *Sthula* (obese) and *Balavan* (Good body strength) in order to correct the *Agni* and to reduce the *Kleda* and *Medas*, which are increased in the disease process of *Prameha*. *Acharya Charaka* has mentioned *Prameha* as *Santarpanajanya Vyadhi* where *Dhatuparinaman* is mainly affected. *Vamana* is the *Apatarpana* type of therapy, which could be helpful by eliminating vitiated *Doshas* corrects *Srotodushti* and *Dhatuparinaman*.

Vamana therapy: Mainly correct, the impaired *Koshtha* and vitiated *Agni*. Help to expel-out the accumulated morbid matters, from all over the body. Act at micro-cellular level and help to maintain the normal physiology of the tissues. Make substratum suitable to increase bioavailability of *Shamana* drug.

Vamaka drug spread from heart to all over body due to its Vyavayi Guna and Anutva Bhava of Sukshma Guna, after attaining its optimal conc. At desired site (receptor and post receptor level) separates, liquefies the stagnated Dosha and Dushya in micro-circulation due to its Ushna Guna, Then these liquefied Doshas and Dushyas at the receptor (insulin binding sites over the cell membrane) and post receptor level (GLUTs) migrate toward the Koshtha, Thus leaving the sufficient number of receptors available to deliver maximum functional ability.

CONCLUSION

In early course of the disease *Samshodhana* must be the choice of treatment as at this stage predominance of *Kapha* and *Pitta Dosha* founds in patients. In order to reduce the obesity of patient and to bring down the *Prameha* condition to normalcy, repeated *Vamana* at specific intervals should be adopted (keeping in mind that, *Bala* of the patient does not detoriate). This would help in obtaining positive results.

According to observations and results of this clinical study it can be concluded that *Vamana* followed by *Nisha-Amalaki Yoga* is significantly reduce fasting and Post Prandial blood sugar level.

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