RESEARCH PAPER

An open-label, single-arm clinical study to evaluate the adjuvant effect of Nishakathakadi Ghanavati in the management of Type 1 Diabetes Mellitus

Dr. Vinod Kumari Yadav[1*] Dr. Vishal Nandlal Prajapati[2] Dr. Nisha Kumari Ojha[3]

[1*]PG Scholar, Kaumarbhritya Department, National Institute of Ayurveda, Deemed to be University, Jaipur, Rajasthan, India-302002, E-Mail Id: kumarivinodyadav810@gmail.com , ORCID: https://orcid.org/0009-0003-5812-6837
[2]Assistant Professor, Kaumarbhritya Department, National Institute of Ayurveda, Deemed to be University, Jaipur, Rajasthan, India-302002, E-Mail Id: vish123go@gmail.com, ORCID: https://orcid.org/0000-0001-6898-1253
[3]Professor, HOD, Kaumarbhritya Department, National Institute of Ayurveda, Deemed to be University, Jaipur, Rajasthan, India-302002, Mail Id: drnishaojha@gmail.com , ORCID: https://orcid.org/0000-0003-0344-4152

Abstract

Introduction: Type 1 Diabetes Mellitus (T1DM) is an autoimmune disorder requiring lifelong insulin therapy, imposing a heavy physical, psychological, and financial burden on children and families. Despite advances in insulin therapy, compliance and quality-of-life challenges persist. Ayurveda describes a comparable condition, Sahaja Prameha, managed with formulations possessing Pramehahara (~Anti-diabetic), Rasayana (~Rejuvenating/antioxidants), and Ojovardhaka (~improves immunity) properties. So, in this study *Nishakathakadi Ghanavati,* a polyherbal preparation, was evaluated as an adjuvant to standard insulin therapy in pre-diagnosed T1DM children.

Methods: An open-labeled, single-arm clinical trial was conducted on 36 T1DM diagnosed patients aged 6-16 years. The trial drug *Nishakathakadi Ghanavati* (750-2500 mg/day) was administered for 90 days alongside insulin therapy. Outcomes included insulin dosage, glycemic parameters (FBS, PPBS, HbA1c, C-peptide), symptom relief, and WHO-QOL scores. Theses parameters were analysed at baseline and post-intervention.

Results: Out of 36 enrolled patients, 30 completed the study. The result showed that daily insulin requirement was reduced significantly by 64.34% ($p < 0.0001$). FBS decreased by 12.51% ($p \leq 0.01$) and PPBS by 10.81% ($p \leq 0.05$). HbA1c showed a 19.75% reduction and C-peptide a 4.45% rise, both non-significant ($p>0.05$). Clinical symptoms improved markedly i.e. weakness/tiredness (48.14%), polydipsia (31.69%), polyuria (29.53%), polyphagia (29.22%), and weight loss (33.33%). WHO-QOL scores improved across social (31.17%), psychological (10.32%), environmental (6.91%), and physical (4.71%) domains. No adverse drug reactions (ADRs) were observed.

Conclusion: *Nishakathakadi Ghanavati* appears safe and moderately effective as an adjuvant in T1DM, significantly reducing insulin requirement, improving symptoms, and enhancing quality of life. Larger, long-term studies are recommended.

Keywords: Adjuvant Therapy, Ayurveda, Juvenile Diabetes, *Nishakathakadi Ghanavati*, Type 1 Diabetes.

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INTRODUCTION

Type 1 Diabetes Mellitus (T1DM), also known as juvenile diabetes, is an autoimmune disorder that destroys pancreatic β-cells and causes severe insulin deficiency.[1] 22,94,000 Indian children aged 0 to 19 are estimated to have type 1 diabetes, according to the International Diabetes Federation Atlas 2021.[2] The overall incidence of T1DM in India is estimated to be 10.5 per 100,000 children per year. However, this figure can vary significantly by region and demographic group. The peak incidence of T1D in India is between 10 and 12 years old.[3] While incidence rates can vary by gender, studies show a relatively equal distribution of T1D between boys and girls. There are also variations in prevalence between rural and urban areas, with lower prevalence often observed in rural areas, possibly due to under diagnosis.[4]

Genetic predisposition, primarily linked to HLA-DQ and DR on chromosome 6, along with environmental factors like infections, contribute to disease onset.[5] Auto-antibodies against GAD, insulin, and IA-2 serve as markers of progression. Despite advances in genetic and antibody testing, the exact cause remains unclear, with family history accounting for only 10-15% of cases. Individuals with type 1 DM confront serious lifestyle alterations that include an absolute daily requirement for exogenous insulin, the need to monitor their glucose control, and the need to pay attention to dietary intake.

Current treatment depends heavily on multiple daily insulin injections and glucose monitoring, which imposes a significant physical and psychological burden on children and their caregivers. Despite advancements in diabetes management technologies, a widely accessible, single, oral therapeutic option remains unavailable. Given the limitations of current therapy, including frequent pricks, risk of hypoglycemia, and poor compliance, there is a clear necessity for alternative or

adjuvant treatments that are safe, affordable, and effective.[6]There is a strong emphasis not only the need for a cure but also on the urgency of developing better treatment modalities that ease disease burden and improve quality of life.

According to Ayurveda Genetic (Sahaja), occurring in young age from the very beginning of life, that has some similarities with juvenile diabetes or insulin-dependent diabetes. This Sahaja type of Madhumeha is due to certain defects in Stri and Pumbeeja (ovum and sperm), which is said to be Matru-pitrubeeja doshakrita (Chromosomal defect from parents), will result in Sahajaprameha.[7] Also, Kashyapa Samhita in the context of Prameha, explained some features as Gaurava (Heaviness in body), Baddhata (stiffness), lassitude and fatigue, Akasmat-mutranirgamah (sudden passage of urine in increased quantity), increased turbidity of urine, and Makshika-akrantah (ants or flies get attracted to the baby's urine).[8]

Jataja Prameha is mainly considered due to Dhatukshaya (~the state of malnutrition at micro cellular level) and Ojakshya (~depletion of Oja), hence, the Nishakathakadi Kashayam[9] with properties like Pramehahara (anti-diabetic), Rasayana (rejuvenating, antioxidants, and antiaging), and Ojovardhaka (improves the health, vitality, and enthusiasm) were selected for the management. By considering the palatability issues in children Nishakathakadi Kashayam form changed to Ghanavati (extract form). Nishakathakadi Ghanavati had Vatakaphahara properties due to Sheeta, Ushna Veerya, and Madhura, Katu Vipaka of drugs helping in alleviating the disease.[10]

Considerable efforts have been made for the development of oral insulin for better patient compliance. However, such options are not yet available in the market and insulin remains the mainstay of treatment of type 1 diabetes. A single, cost-effective, oral, antidiabetic treatment with minimal side effects is the need of the day. At present there was no study available that address any effect of Nishakathakadi Ghanavati in juvenile diabetes So, this trial was designed to evaluate the effect of Nishakathakadi Ghanavati along with its safety and efficacy in pre-diagnosed cases of T1DM (Juvenile Diabetes).

MATERIALS & METHODS

Study Type: The current trial was an open-labeled single arm interventional clinical trial

Selection of Patients: Diagnosed cases of T1DM (Juvenile Diabetes) were selected from the OPD of Kaumarabhritya (Balroga), National Institute of Ayurveda, deemed to be a university, Jaipur, for this research work.

This trial was ethically approved by the Institutional Ethics Committee of the National Institute of Ayurveda, Deemed to be University, Jaipur, with IEC Reference number IEC/ACA/2022/02/9 on date 10/10/2022 and was prospectively registered at CTRI with registration No. CTRI/2023/07/054655 in April 2023.

Participants: A total of 36 pre-diagnosed children with T1DM, aged between 6 and 16 years of either gender were recruited in the study.

Trial drug: The trial drug was Nishakathakadi Ghanavati. Its ingredients were as mentioned in Table No. 1.

Drug Interventions: The trial drug was intervened to recruited children of T1DM as mentioned in table No. 2

Criteria for selection of cases:

Inclusion Criteria

1.Age group 6 years to 16 years of age of either sex.

2.Pre-diagnosed cases of T1DM (Juvenile diabetes)

3.Patients having FBS ≥126mg/dl, PPBS ≥200 mg/dl, HbA1c ≥6.5%

Exclusion Criteria

1. Children below 6 years and above 16 years.
2. Children with a tendency to have recurrent DKA (Diabetic Keto Acidosis).
3. Children with complications of diseases like diabetic foot.
4. Children with another infectious disease, such as TB etc, metabolic disease, other endocrinal disease, or genetic anomalies.
5. Patients having FBS <126mg/dl, PPBS <200 mg/dl, HbA1c <6.5%

Outcome Measures:

Primary outcome measure was reduction in total per day dose of insulin whereas secondary outcome measures were changes in laboratory investigations like FBS, PPBS, and HbA1c and improvement in the WHO-QOL of children with Juvenile diabetes.

Assessment Criteria:

Laboratory parameters: Biochemical investigations i.e. FBS (Fasting Blood Sugar), PPBS (Postprandial Blood Sugar), HbA1c, C-peptide test.

Subjective Criteria

The subjective criteria i.e. changes in symptoms like Weakness/Tiredness, Polydipsia, Polyuria, Polyphagia, Weight loss [Table No. 3] and WHO-QOL were assessed before & after treatment.

Data Documentation and Analysis

Observations collected during the study were analyzed, and findings were analyzed by using appropriate statistical methods.

OBSERVATIONS

The observational study (as mentioned in table no. 4) analyzed 36 subjects with Type 1 Diabetes Mellitus (T1DM). The majority (72.22%) were aged 6-12 years, with an equal distribution of males and females. Most belonged to the lower middle class (69.44%), and polyphagia (80.55%), weakness (58.33%), and weight loss (55.55%) were the most common complaints, with polyuria noted in 50%. Diagnosis occurred mainly between 5-10 years (44.44%), and chronicity of 1-2 years was observed in 38.88%. All subjects were on insulin, with 61.11% receiving pre-mixed (Rapid + Long-acting)

insulin. A positive family history was seen in 25%, and most were born full-term (94.44%) with normal delivery (75%) and adequate birth weight (75%). Nutritionally, 94.44% followed a vegetarian diet, and exclusive breastfeeding was practiced until 6 months in 44.44%. However, 94.44% were underweight, and 72.22% had low physical activity.

RESULT

Figure 1 depicts the CONSORT flow chart for the subject's par ticipation in the study. A total of 30 patients with Type 1 Diabetes Mellitus (T1DM) completed the 90-day intervention with Nishakathakadi Ghanavati. Significant improvements were observed in key glycemic parameters. Fasting Blood Sugar (FBS) reduced by 12.51% ($p \leq 0.01$), and Postprandial Blood Sugar (PPBS) by 10.81% ($p \leq 0.05$). HbA1c levels decreased by 19.75%, though not statistically significant ($p > 0.05$). C-peptide levels showed a mild, non-significant rise (4.45%). [Table No. 5]

Table No. 6 presents that insulin requirement reduced significantly, with a 64.34% reduction from baseline to day 90 ($p < 0.0001$), and 90% of patients showed decreased insulin dosage post-treatment. Core diabetic symptomspolyuria, polydipsia, polyphagia, fatigue, and weight loss, showed 29% to 48% relief, all statistically significant ($p < 0.01$).

As per Table No.7 the Quality of Life (WHO-QOL) improved across all domains social (31.17%), psychological (10.32%), environmental (6.91%), and physical (4.71%), with overall QoL improvement of 13.27% ($p < 0.001$).

The therapy demonstrated significant improvement in key symptoms of Type 1 Diabetes Mellitus. Table No. 8 shows that polyuria reduced by 29.53% ($p = 0.0005$), polydipsia by 31.69% ($p = 0.0002$), polyphagia by 29.22% ($p < 0.0001$), weakness/tiredness by 48.14% ($p = 0.0002$), and weight loss by 33.33% ($p = 0.0020$). All improvements were statistically significant ($p < 0.01$), indicating effective symptom control.

DISCUSSION

Nishakathakadi Ghanavati comprises equal parts of Haridra, Kataka, Amalaki, Techiver, Lodhra, Bhadrika, Ekanayakam, and Ramacham. These ingredients are well-known for their antioxidant, immunomodulatory, and antidiabetic properties. In managing Jataja Prameha, which arises from Dhatukshaya and Ojakshaya, herbs with Pramehahara, Rasayana (rejuvenating and antiaging), and Ojovardhaka (enhancing vitality) actions were chosen. Since Kapha, Vata, and Meda Dushti contribute to Madhumeha, Nishakathakadi Ghanavati's Vata-kaphahara properties, due to Sheeta, Ushna Veerya, and Madhura-Katu Vipaka aid in disease alleviation. As shown in Table No. 9, recent studies confirm the hypoglycemic activity of these herbs, supporting their use in diabetes management.[11]

The administration of Nishakathakadi Ghanavati in Type 1 Diabetes Mellitus (T1DM) patients demonstrated a multifaceted and moderately positive impact across various clinical and subjective parameters, highlighting its potential as a complementary therapy alongside conventional insulin treatment. The therapy significantly improved glycemic control by reducing Fasting Blood Sugar (FBS) by 12.51% and Postprandial Blood Sugar (PPBS) by 10.81%, indicating better glucose metabolism and post-meal glucose management. However, the 19.75% reduction in HbA1C, though notable, was not statistically significant ($p > 0.05$), suggesting that the 3-month intervention periods may have been insufficient for substantial long-term glycemic improvements, and a longer duration or adjunctive therapies may be required to observe more pronounced changes. C-peptide levels, reflecting endogenous insulin secretion and pancreatic beta-cell function, showed a 4.45% increase. One of the most remarkable findings was the significant reduction in insulin dosage requirements, with decreases of 27.82% by the 30th day, 46.95% by the 60th day, and 64.34% by the 90th day ($p < 0.05$), suggesting enhanced insulin sensitivity and better glucose utilization, thereby reducing the dependency on exogenous insulin. Although the most notable dose adjustments occurred in the initial phase of therapy, the overall reduction of 50.60% between the 30th and 90th days highlights the progressive efficacy of the intervention. Improvements in chief complaints, such as polyuria, polydipsia, polyphagia, weakness/tiredness, and weight loss, were also observed, with weakness/tiredness showing the highest improvement at 48.14%, likely due to better glycemic control and reduced catabolic effects. Quality of Life (QoL), assessed through WHO-QOL parameters, showed mild to moderate improvements across all domains, with the social domain exhibiting the highest improvement at 31.17%, possibly due to better disease management and improved social interactions. Psychological and environmental domains showed modest gains of 10.32% and 6.91%, respectively, reflecting reduced stress and improved overall well-being. Despite these positive effects, the overall impact on QoL was mild (13.27%), suggesting that while Nishakathakadi Ghanavati contributes to better metabolic outcomes and symptom relief, additional lifestyle modifications and supportive interventions may be necessary to maximize long-term benefits.No any adverse drug reactions were noticed during the trial period.The findings underscore the potential of Nishakathakadi Ghanavati in enhancing insulin sensitivity, alleviating symptoms, and improving immune function, making it a valuable adjunct in the holistic management of type 1 diabetes mellitus (T1DM).

CONCLUSION

The clinical study suggests that Nishakathakadi Ghanavati is an effective adjuvant therapy in managing Type 1 Diabetes Mellitus (T1DM). It significantly reduced insulin requirements and improved common symptoms like fatigue, weight loss, polyuria, and polydipsia. Although changes in HbA1c and C-peptide were not statistically significant, the overall improvement in glycemic control, symptom relief, and quality of life indicates its potential supportive role. The observed

benefits may be attributed to its Pramehahara, Rasayana, and Ojovardhaka properties.

Authors Contribution:
1. V.K. - Conceptualization, Methodology, Data collection, Data analysis
2. V.N.P.- Conceptualization, Methodology, Writing the original draft, Validation, Formal Analysis, Supervision
3. N.K.O.- Conceptualization, Methodology, Reviewing, Editing, Validation, Formal Analysis, Supervision

Declaration of Generative AI in scientific writing:
Generative AI and AI-assisted technologies were not used in writing this manuscript.

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Table No.1: Ingredients of Trial Drug- Nishakathakadi Ghanavati [9]

Ingredients	Botanical Name	Root	Part Used
Haridra	Curcuma longa Linn.	Bark	Heart wood
Kataka	Strychnos potatorum Linn.	Loganiaceae	Seed
Amalaki(Nellikka)	Emblica officinalis Gaertn.	Phyllanthaceae	Fruit rind/pericarp
Techiver (Sindurimula)	Ixora coccinea Linn.	Rubiaceae	Root
Pachotti (Lodhra)	Symllocos racemosa Roxb.	Symplocaceae	Bark
Bhadrika (Gorakshganja)	Aerva lanata Juss.	Amaranthaceae	Root
Ekanayakam (Ekrangi)	Salacia chinensis Linn.	Hippocrateaceae	Root
Ramacham (Usheera)	Vetiveria zinanioides Linn.	Gramineae	Root

Table No.2: Mode of Intervention

Dosage form	*Ghanavati*
Dose	750-2500 mg (calculated as per Sharangadhar formula with adult dose 1.25gm -2.5 gm/day)
Anupana	Luke warm water
Route of administration	Oral
Time of administration	Before meals
Duration of therapy	90 days
Post Intervention period	30 days

Table No.3: Scoring pattern - Gradation of Symptoms of Type 1 DM[12]

Weakness/Tiredness

Grade 0	No weakness in routine work
Grade 1	Weakness in routine work, but able to cope up
Grade 2	Weakness is enough to hamper routine work
Grade 3	Weakness in slight work or at rest, requiring bed rest

Polydipsia

Grade 0	Need a normal amount of water to satisfy quench

Grade 1	Need water twice than normal to satisfy quench
Grade 2	Need water three times the normal to satisfy quench
Grade 3	Not satisfying even after drinking abundant water

Polyuria (More marked at night)

Grade 0	Frequency of urine output >6 times per day
Grade 1	Frequency of urine output >8 times per day
Grade 2	Frequency of urine output >10 times per day
Grade 3	Frequency of urine output >15 times per day

Polyphagia

Grade 0	Normal appetite
Grade 1	Need twice the amount of food to satisfy hunger
Grade 2	Need thrice the amount of food to satisfy hunger
Grade 3	Not satisfied even after consuming abundant amounts of food

Weight loss

Grade 0	No weight loss
Grade 1	Mild to moderate weight loss
Grade 2	Moderately severe to severe weight loss
Grade 3	Extreme weight loss, so that patient is unable to even walk by himself

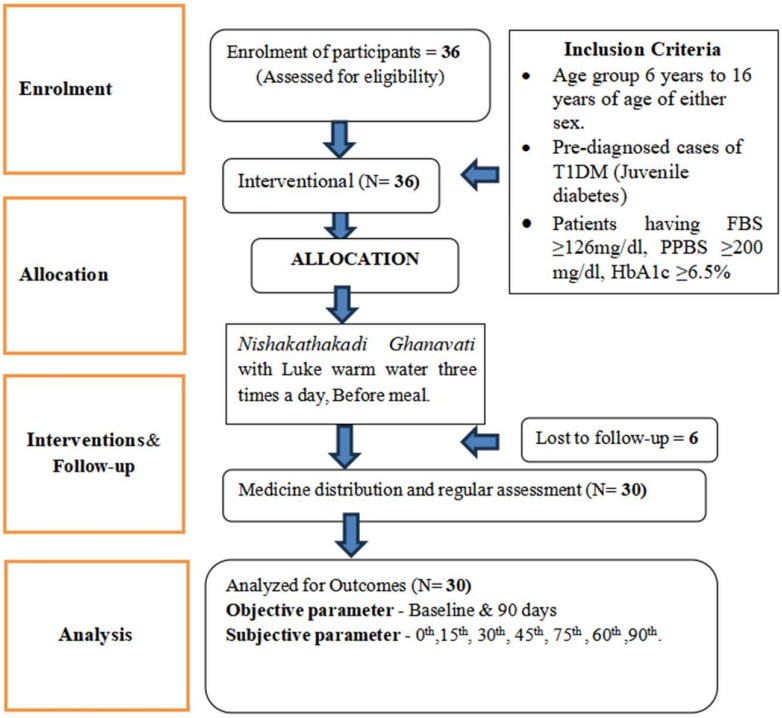

Fig.1: CONSORT Flow chart

Table No.4: Basic details of observations

S.N.	Feature	Classification	Total Subjects (N= 36)	
			No.	%
1	Age	6-9 Years	13	36.11%
		9-12 Years	13	36.11%
		12-16 Years	10	27.77%
2.	Sex	Male	18	50%
		Female	18	50%
3.	Religion	Hindu	35	97.22%
		Muslim	1	2.77%
4.	Habitat	Urban	22	61.11%
		Rural	14	38.88%
5.	Socio-economic status	Upper	0	0%
		Upper Middle	5	13.88%
		Lower Middle	25	69.44%
		Upper Lower	4	11.11%

		Lower	2	5.55%
6.	Chief complaints	Polyuria (More marked at night)	18	50%
		Polydipsia	16	44.44%
		Polyphagia	29	80.55%
		Weakness/Tiredness	21	58.33%
		Weight loss	20	55.55%
7.	Associated complaints	Celiac Disease	08	22.22%
		Urinary tract infection	02	5.55%
		Nil	24	66.66%
8.	Age of Diagnosis	<1 year	0	0%
		1-5 years	8	22.22%
		5-10 years	16	44.44%
		>10 years	12	33.33%
9.	Chronicity	<1 year	02	5.55%
		1-2 years	14	38.88%
		2-3 years	07	19.44%
		3-4 years	05	13.88%
		4-5 years	08	22.22%
		> 5 years	00	0%
10.	History of taking Insulin therapy	Yes	36	100%
		No	0	0%
11.	Type of Insulin	Rapid-acting	0	0%
		Short-acting	1	2.77%
		Intermediate-acting	1	2.77%
		Long-acting	0	0%
		Pre-mixed (Rapid+Long)	22	61.11%
		Pre-mixed (Rapid + Intermediate)	12	33.33%
12.	Total per day dose of Insulin	0-10 Units	02	5.55%
		10-20 Units	12	33.33%
		20-30 Units	09	25%
		30-40 Units	06	16.66%

		40-50 Units	03	8.33%
		50-60 Units	02	5.55%
		>60 Units	02	5.55%
13.	Family history of T1DM	Positive	9	25%
		Negative	27	75%
14.	Age of Mother (years)	<20 Years	2	5.55%
		20-25 Years	14	38.88%
		25-30 Years	20	55.55%
		>30 Years	0	0%
15.	Nature of Delivery	Normal	27	75%
		Vacuum/Forceps	0	0%
		LSCS	09	25%
16.	Term of Gestation	Preterm	2	5.55%
		Full term	34	94.44%
		Post-term	0	0%
17.	Birth Weight (kg)	<2.5kg (LBW)	6	16.66%
		2.5-3.5kg (AGA)	27	75%
		>3.5 kg (LGA)	3	8.33%
18.	H/O Breast Feeding	Exclusive till 6 months	16	44.44%
		Artificial fed	00	00%
		BF (Breast Feeding) + AF (Artificial fed)	20	55.55%
19.	Weaning	Early	20	55.55%
		Proper/Normal	11	30.55%
		Late	05	13.88%
20.	Immunization	Proper	35	97.22%
		Improper	1	2.77%
21.	BMI	Obese (>25)	00	0%
		Underweight (<18.5)	34	94.44%
		Normal (18.50-24.99)	2	5.55%
22.	Nature of food	Vegetarian	34	94.44%
		Mixed	2	5.55%

23.	Appetite	Good	17	47.22%
		Moderate	03	8.33%
		Poor	0	0%
		Excessive	16	44.44%
24.	*Nidra* (Sleep)	*Samyaka*(Appropriate /Sound sleep) (6-8hrs)	22	61.11%
		Alpa(Poor) (<6 hrs)	0	0%
		Prabhuta(Excess) (>10 hrs)	14	38.88%
25.	*Mutra Pravritti* (Urine frequency)	*Samyaka*	05	13.88%
		Prabhuta	31	86.11%
26.	*Prakriti* (~Body Constitution)	*Vata*	0	0%
		Pitta	0	0%
		Kapha	0	0%
		Vata Pitta	17	47.22%
		Pitta Kapha	8	22.22%
		Vata Kapha	11	30.55%
		Tridosha	0	0%
27.	*Aharana Shakti* (Intake of Meal)	*Uttama*	27	75%
		Madhyama	09	25%
		Hina	00	0%
28.	*Vyaayama Shakti* (Playing Activity/Day)	*Pravara*(>3 hrs/day)	00	0%
		Madhyama(2-3 hrs/day)	10	27.77%
		Avara(1-2 hrs/day)	26	72.22%
29.	*Vaya* (Age)	*Sheerapa*	00	0%
		Ksheeraannaada	00	0%
		Annaada	36	100%
30.	*Aharaja Nidana Sevana* (Dietary Causes) of child	*Dadhi /Mandakadadhi.* (Habitual intake of curd)	26	72.22%
		Intake of meats and soups of different *Anupa*, *Audaka*, and *Gramya* animals)	01	2.7%
		Paya(Use of milk and its products)	20	55.55%
		Navaanna(Use of early-ripened pulses and grains)	18	50%

		Gudavikruti(Use of sugarcane and its productslike Guda, *Khanda*, *Sharkara*, and *Sugar*).	14	38.88%
31.	*Aharaja Nidana Sevana* (Dietary Causes) of Mother during pregnancy	*Dadhi /Mandakadadhi.* (Curd)	23	63.88%
		Intake of meats and soups of different *Anupa*, *Audaka*, and *Gramya* animals.)	01	2.7%
		Paya(Use of milk and its products)	09	25%
		Navaanna(Use of early-ripened pulses and grains)	16	44.44%
		Gudavikruti(Use of sugarcane and its productslike Guda, *Khanda*, *Sharkara*, and *Sugar*)	13	36.11%
32	*Diwaswapna* (Day sleeping)	Yes	22	61.11%
		No	14	38.88%

Table No.5: Statistical analysis of investigations

	N	**BT (Mean±S.D.)**	**AT (Mean±S.D.)**	**Mean change**	**±S.D.**	**±S.E.**	**'t'**	**P**	**% Change**	**Results***
FBS	30	243.4±95.17	213.0±78.86	30.42	44.71	8.163	3.727	≤ 0.01	12.51%	Sig
PPBS	30	403.2±94.83	359.6±74.92	43.61	51.76	9.451	4.615	≤0.05	10.81%	Sig
HbA1C	30	12.40±2.407	9.947±1.647	2.449	177.0	32.32	0.9249	>0.05	19.75%	NS
C-Peptide	30	0.2245±0.1935	0.2345±0.1636	0.01000	0.1203	0.02233	0.4478	>0.05	4.45%	NS

Paired t-test*[BT = Before Treatment, AT = After Treatment, S.D. = Standard Deviation, S.E. = Standard Error, Sig.- Significant, NS- Non-significant]

Table No.6: Statistical presentation of Insulin dose

	N	**Rank sum score**			**Mean diff**	**±S.D**	**±S.E**	**Z Value**	**P Value**	**% Change**	**Results***
		Baseline	30th Day	X							
Baseline vs. 30th Day	30	115	83	32	4.27	1.92	0.351	3.2	0.0082	27.82%	Sig
Baseline vs. 60th Day	30	115	61	54	7	3.08	0.561	5.4	<0.0001	46.95%	Sig

Baseline vs. 90th Day	30	115	41	74	9.4	4.81	0.878	7.4	<0.0001	64.34%	Sig
30th Day vs. 60th Day	30	83	61	22	2.73	1.16	0.21	2.2	0.1668	26.50%	NS
30th Day vs. 90th Day	30	83	41	42	9.4	4.81	0.941	4.2	0.0002	50.60%	Sig
60th Day vs. 90th Day	30	61	41	20	2.4	1.73	0.317	2	0.2730	48.78%	NS

ANOVA test* Friedman test* [BT = Before Treatment, AT = After Treatment, S.D. = Standard Deviation, S.E. = Standard Error, Sig.- Significant, NS- Non-significant]

Table No.7: Effect of Therapy on WHO-QOL (Quality of Life) in T1DM patients:

WHO-QOL	N	BT (Mean±S.D.)	AT (Mean±S.D.)	Mean change	±S.D.	±S.E.	't'	P	% Change	Results*
Physical	30	63.55±3.230	66.54±3.315	2.994	3.256	0.5944	5.037	<0.0001	4.71%	Sig
Psychological	30	57.85±7.824	63.82±7.230	5.971	8.186	1.495	3.995	0.0004	10.32%	Sig
Social	30	21.39±5.220	28.05±5.987	6.668	5.538	1.011	6.595	<0.0001	31.17%	Sig
Environment	30	45.21±1.784	48.33±2.283	3.125	1.835	0.3350	9.327	<0.0001	6.91%	Sig

Paired t-test*[BT = Before Treatment, AT = After Treatment, S.D. = Standard Deviation, S.E. = Standard Error, Sig.- Significant]

Table No.8: Statistical presentation of Chief Complaints

Chief Complaints	N	BT (Mean±S.D.)	AT (Mean±S.D.)	Mean change	±S.D.	±S.E.	W	P	% Change	Results*
Polyuria (More marked at night)	30	1.467±1.306	1.033±0.9279	0.4333	0.5683	0.1038	78	0.0005	29.53%	Sig
Polydipsia	30	1.367±1.351	0.9333±0.9444	0.4333	0.5040	0.09202	91	0.0002	31.69%	Sig
Polyphagia	30	2.167±0.7466	1.533±0.5713	0.6333	0.4901	0.08949	190	<0.0001	29.22%	Sig
Weakness/	30	0.9000±0.8030	0.4667±0.5074	0.4333	0.5040	0.09202	91	0.0002	48.14%	Sig

Tiredness										
Weight loss	30	1.000±0.8305	0.6667±0.6065	0.3333	0.4795	0.08754	55	0.0020	33.33%	Sig

Wilcoxon test* [BT = Before Treatment, AT = After Treatment, S.D. = Standard Deviation, S.E. = Standard Error, Sig.- Significant]

Table No.9: Pharmacological actions of Nishakathakadi Ghanavati

S.N.	Ingredients	Ayurveda pharmacological Action	Modern Pharmacological Action
1.	*Haridra*	*Kapha-pitta* pacifying, *Mehahara*[13,14,15] (anti-diabetic).	Anti-oxidant activity[16,17] Immunomodulatory activity[18,19] Anti-diabetic activity[20,21]
2.	*Amalaki* *(Nellikka)*	*Tridoshahara*, *Rasayana.*[22] (Rejuvenation & Immunomodulating)	Anti-oxidant activity[23,24,25] Immunomodulatory activity[26] Anti-diabetic activity[27,28]
3.	*Kataka*	*Kapha-vatahara, Chakshusya, Mehanashanam*[29] (anti-diabetic)	Anti-diabetic activity[30] Anti-inflammatory effect.[31,32] Antioxidant activity[33]
4.	*Techiver (Paranti)*	*Pittaghana Karma*[34]	Anti-oxidant activity[35] Hypoglycaemic and Hypolipidaemic Activity[36]
5.	*Pachotti* *(Lodhra)*	*Pramehahara*[37] (anti-diabetic)	Anti-oxidant activity, Anti-diabetic activity, Immunomodulatory activity[38]
6.	*Bhadrika* *(Gorakshganja)*	*Pramehahara*[39] (anti-diabetic)	Anti-oxidant activity[40] Anti-diabetic activity[41]
7.	*Ekanayakam (Ekrangi)*	*Madhumehaghni*[42] (anti-diabetic)	Anti-oxidant activity[43,44] Anti-diabetic activity[45]
8.	*Ramacham (Usheera)*	*Pramehahara*[42] (anti-diabetic)	Antioxidant activity[46,47] Antidiabetic activity[48]