A placebo controlled clinical trial to assess the efficacy of *Gayatriadi Yoga Vati* as an add on intervention in the management of *Jataja Prameha* w.s.r. to Juvenile Diabetes in children

Introduction:

Diabetes is a heterogenous group of metabolic diseases characterized by hyperglycemia and glycosuria, which gradually leads to serious multi-organ dysfunctions including retinopathy, neuropathy, nephropathy, dyslipidemia and much more. The most common variety is type 2 diabetes, usually in adults, which occurs when the body becomes insulin resistant (IR) or doesn't make enough insulin. In the past three decades the prevalence of type 2 diabetes has risen dramatically in countries of all income levels. Type 1 diabetes, once known as juvenile diabetes or insulin-dependent diabetes, is a predominantly autoimmune (95%) or idiopathic (5%) disorder in which there is absolute insulin deficiency due to the destruction of pancreatic beta cells, the clinical manifestations of which occur once more than 80% of beta cells are destroyed. For people living with diabetes, access to affordable treatment, including insulin, is critical to their survival.[i] Type 1 and type 2 diabetes affect about 186,000 youth under age 20. Previously considered an adult disease, type 2 diabetes is becoming increasingly common in overweight minority youth over 10 years of age.[ii] Prevalence of T1DM in general Indian population is 8.9%.[iii]

Ayurveda classics explained extensively on the disease *Prameha*, but the references regarding *Jataja Prameha* is utmost minimal. One important and most commonly available reference is in Kashyapa Samhita (*Vedanaadhyaya- Sutrasthana)* that discusses about the prodromal signs and symptoms of *Prameha.*[iv] Thus there is no much direct information regarding the *Prameha* in children nor any special line of treatment or medications in any of the Ayurvedic texts. So the fundamental principles for the *Prameha Chikitsa* for adult with adequate modifications are applied in this study.

From the Ayurveda perspective, for a disease of *Sahaja* nature, wherein *Dhatukshaya* is seen, the classical approach is applied i.e. the use of *Shodhana* therapy followed by use of *Rasayana* (Rejuvenating, antioxidants, and anti-ageing) to protect the body tissues from destruction. Considering the conditions in children with *Prameha*, the drugs used for the treatment for *Jataja Prameha* should have *Pramehahara* and *Rasayana* properties.

Gayatriadi Yoga is mentioned in Ashtangahridaya *Prameha Chikitsadhyaya.* The contents are *Khadira, Vidanga, Daruharidra* and *Dhava.* Even though *Gayatriadi Yoga* is mentioned in the context of *Kaphaja Prameha,* it is chosen for this research because, many Ayurvedic

practitioners in Kerala use this combination in T1DM. As per the available information, no any researches have been conducted on this combination, hence this combination is selected for the study. While analysing the individual drugs the anti-diabetic properties are evident. Priya Nighantu describes *Daruharidra* as an excellent medicine in *Yakrit vikaras* along with its *Pramehaharatwa*.[v] Similarly Kaiyadeva Nighantu explains the rest three drugs as useful in diabetes.[vi, vii]As the disease is *Yapya* (very difficult to cure) in nature, complete cure is not possible. But we can reduce the insulin dose and improve the quality of life of suffering children.

Aim and objective:

To evaluate the efficacy of *Gayatriadi Yoga Vati* as an add on intervention in the management of *Jataja Prameha* (Juvenile Diabetes).

Materials and methods:

It was an open labelled randomized placebo controlled clinical trial. Approval for design of the study and ethical clearance were obtained from institutional ethical committee of ITRA, Jamnagar (PGT/7/-A/Ethics/2022-23/2346 dated 25/02/2023). The clinical trial has been registered in Clinical Trials Registry – India (CTRI), having registration number CTRI/2023/04/051313 dated 05/04/2023.

Selection of Patients: Pre diagnosed and freshly diagnosed patients of Type 1 diabetes being treated with conventional treatment modalities attending the OPD of Dept. of Kaumarbhritya, ITRA, Jamnagar and those selected through medical camps fulfilling the criteria of inclusion who are willing to participate in this study were selected.

Inclusion criteria:

- Diagnosed cases of Type 1 Diabetes within the age group of 2-16 years, irrespective of gender.

Exclusion criteria:

- Children less than 2 years and greater than 16 years of age.
- Children with other infectious diseases such as TB, Immune compromised children, HbSAg, Other metabolic diseases, Genetic anomalies.
- Children with complications of disease like Coronary Artery Disease, Diabetic foot, Nerve damage, Kidney damage.

- FBS> 500 mg/dL.

Posology

- The dose of drug administration is calculated based on **Sharangadhara Samhita** dose fixation guidelines[viii] i.e.- (*16 years to 70 years – Adult dose)

$$\text{Child Dose} = \frac{\text{Adult Dose}}{16} \times \text{Age of child in years}$$

- Adult dose of both formulations in tablet form= 6 gm/ day

Table 01: Dose of *Gayatriadi Yoga Vati* and Placebo *Vati* according Age Group

Age Group	**Dose**
2 - 5 Yrs.	3 *Vati* (1.5 gms)
> 6 – 9 Yrs.	6 *Vati* (3 gms)
>10 – 13 Yrs.	9 *Vati* (4.5 gms)
>14 – 16 Yrs.	12 *Vati* (6 gms)

Table 02: Posology of the drug

Drug	***Gayatriadi Yoga Vati* and Placebo *Vati***
Formulation	*Vati*
Anupana	Luke warm water
Kaala	*Pragbhakta*
Duration	12 weeks
Follow up	4 weeks

CRITERIA OF ASSESSMENT:

A clinical proforma was prepared to study the etiopathogenesis and response to the given treatment and to record any complications if occurred (Annexure 2).

The assessment was done after the treatment mentioned below:

1. Changes in the objective parameter.
2. Changes in the subjective parameter.

- **Objective Criteria:**

All the below-mentioned investigations were done to assess the changes in objective parameters. (Before & after treatment)

1. Biochemical investigation – FBS, PP2BS, HbA1c (in all patients), and C- peptide (in randomly selected patients)
2. Changes in the dose of insulin injections.

- **Subjective Criteria**

The subjective criteria for assessment were assessed**.** (Before & after treatment)

- Changes in symptoms:
  - Polyuria (More marked at night)
  - Polydipsia
  - Polyphagia
  - Weakness/Tiredness
  - Weight loss
  - Body aches

Table 03: Scoring pattern - Gradation of Symptoms

Gradation for Type 1 DM:

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 normal amount of water to satisfy quench
Grade 1	Need water twice than normal to satisfy quench
Grade 2	Need water thrice than 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

Body aches

Grade 0	No body ache
Grade 1	Mild body ache, but does not disturb routine activities

Grade 2	Continuous body ache, but does not disturb routine activity
Grade 3	Severe continuous body ache disturbing routine activity

Presentation of data:

Patients' demographic data and information pertaining *Jataja Prameha* (type 1 diabetes mellitus) were obtained from a clinical trial and presented in tabular form for a total of 20 patients. Statistical software was used to analyze the data of 20 patients.

Before and after treatment on non-parametric data - Wilcoxon signed rank test
Before and after treatment on Parametric data - Student's paired t-test
Between the groups on parametric data - Student's unpaired t test
Between the groups on non-parametric data - Mann-Whitney test

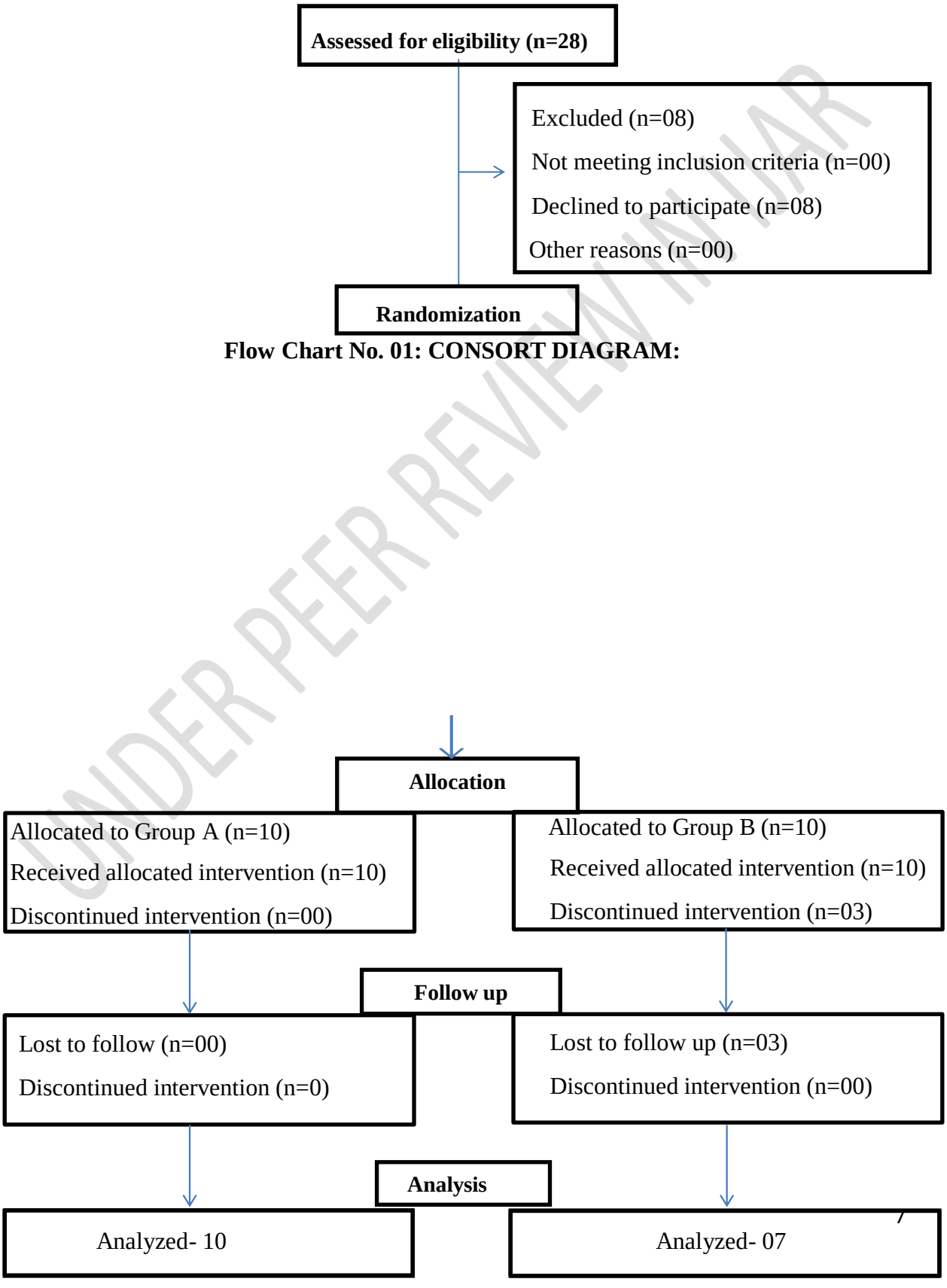
Sigma Stat 3.5 software was used to conduct the tests. The relevant 'p' value against a particular degree of freedom was indicated on the 'Table of 't" after getting the 't' value.

The generated 'p-value findings were interpreted as follows:

- Insignificant (I) - > 0.05
- Significant (S) - < 0.05, < 0.01
- Highly significant (HS) - < 0.001

Observation and Results:

Total 20 patients were enrolled in the present clinical study, out of which, 10 patients were enrolled in group A and 10 patients were in group B. Except 3 patients from group B, rest of the patients completed the treatment in both the groups.



Flow Chart No. 01: CONSORT DIAGRAM:

Effect of Therapy on Chief Complaints in group A (GYV) [n=10]

Table 04: Effect of Therapy on Chief Complaints: Group A (GYV)

Chief Complaints	Mean		Mean Diff.	% Relief	W	P value	P
	BT	AT					
Polyuria (More marked at night)	1.2	0.4	0.8	66.66	-10	0.125	>0.05
Polydipsia	1	0.4	0.6	60	-6	0.250	>0.05
Polyphagia	1.22	0.33	0.89	72.95	-28	**0.016**	<0.05
Weakness/ Tiredness	1.11	0	1.11	100	-45	**0.004**	<0.05
Random body aches	1.16	0	1.16	100	-21	**0.031**	<0.05
Weight loss	0.66	0.33	0.33	50	-15	0.426	>0.05

A statistically significant difference was found ($p < 0.05$) in chief complaints viz. polyphagia, weakness and random body aches in Group A (GYV) with relief of 72.95%, 100% and 100% respectively. The chief complaints polyuria and weight loss remained statistically insignificant though showed relief of 66.66% and 50% respectively.

Effect of Therapy on Chief Complaints in Group B (PBV) [n=07]

Table 05: Effect of Therapy on Chief Complaints: Group B (PBV)

Chief Complaints	Mean		Mean Diff.	% Relief	W	P value	P
	BT	AT					
Polyuria (More marked at night)	1	0.57	0.42	42	-6	0.25	>0.05
Polydipsia	0.28	0	0.28	100	-3	0.5	>0.05
Polyphagia	0.57	0.28	0.28	49.1	-3	0.5	>0.05
Weakness/ Tiredness	0.28	0.14	0.14	50	-1	1	>0.05
Random body aches	0.71	0.14	0.57	80.28	-10	0.125	>0.05
Weight loss	0.28	0.14	0.14	50	-1	1	>0.05

Statistically insignificant differences were found in all parameters viz. polyuria, polydipsia, polyphagia, weakness, random body aches and weight loss in Group B (PBV). 100% relief

was found in polydipsia. Around 80% relief was observed in random body aches. 50% relief could be found in weakness as well as weight loss whereas 49% relief was observed in the parameter polyphagia.

Effect of Therapy on Bio-chemical parameters:

Table 06: Effect of Therapy on Bio-chemical Parameters – Group A (GYV)

Biochemical parameter	Mean		Mean Diff.	% Relief	SD±	t	P value	P
	BT	AT						
FBS	220.9	174.7	46.2	20.9	23.1	1.569	0.151	>0.05
PP_2BS	408.6	316.4	92.2	22.56	46.1	1.444	0.183	>0.05
HbA_1c	10.46	9.75	0.71	6.78	0.355	0.972	0.357	>0.05
C-peptide	0.403	0.420	-0.0175	-0.043	0.008	-0.043	0.969	>0.05

In group A (GYV) there were no statistically significant **(**P <0.05) differences in any of the parameters viz. fasting blood sugar, post prandial blood sugar, glycosylated hemoglobin and c-peptide and showed percentage relief of 20.9%, 22.56%, 6.78% and -0.043% respectively.

Effect of Therapy on injectable Insulin dose – Group A (GYV)

Table 07: Effect of Therapy on injectable Insulin dose – Group A (GYV)

Insulin Dose	Mean		Mean Diff.	% Relief	SD±	t	P value	P
	BT	AT						
Insulin	27.7	23.8	3.9	14.07	1.95	2.935	0.017	<0.05

A significant **(**p <0.05) difference was found in injectable Insulin dose in group A (GYV) at the end of therapy with relief of 14.07%.

Effect of Therapy on Bio-chemical Parameters – Group B (PBV)

Table 08: Effect of Therapy on Bio-chemical Parameters – Group B (PBV)

Biochemical parameter	Mean		Mean Diff.	% Relief	SD±	t	P value	P
	BT	AT						
FBS	216	228.74	-12.714	-5.88	6.37	-0.22	0.832	>0.05
PP_2BS	259	316	-57	-22	28.5	0.569	0.590	>0.05
HbA_1c	9.3	9.786	-0.486	-5.22	0.243	-0.586	-0.579	>0.05

C-peptide	0.2	0.145	0.055	27.5	0.027	1	0.5	>0.05

In group B (PBV) there were no any statistically significant **(**P <0.05) differences found at the end of the therapy though the percentage relief were -5.88, -22, -5.22 and 27.5 respectively for FBS, PPBS, HbA_1c and c-peptide.

Effect of Therapy on Insulin dose – Group B (PBV)

Table 09: Effect of Therapy on Insulin dose – Group B (PBV)

Insulin Dose	**Mean**		**Mean Diff.**	**% Relief**	**SD±**	**t**	**P value**	**P**
	BT	**AT**						
Insulin	29.429	26.857	2.57	8.73	1.286	0.464	0.65	>0.05

Statistically insignificant **(**p >0.05) difference was found in injectable Insulin dose in group B (PBV) at the end of therapy with relief of 8.73%. (Table 8.45)

Comparative effect of Therapy between the group A (GYV) and group B (PBV) (N=17)

Comparative effect of Therapy on Chief Complaints between the Group A (GYV) and Group B (PBV) (N=17)

Table 10: Effect of Therapy on Chief Complaints between the groups

Chief complaints	**Group**	**Mean diff.**	**% Relief**	**SD±**	**U**	**P**
Polyuria (More marked at night)	A	0.8	66.66	0.4	39	0.68
	B	0.42	42	0.215		
Polydipsia	A	0.6	60	0.3	35.5	1
	B	0.28	100	0.14		
Polyphagia	A	0.89	72.95	0.445	46	0.247
	B	0.28	49.1	0.145		
Weakness/ Tiredness	A	1.11	100	0.555	62	**0.003**
	B	0.14	50	0.07		
Random body aches	A	1.16	100	0.58	38	0.783
	B	0.57	80.28	0.285		

Weight loss	A	0.33	50	0.94	9.5	1
	B	0.14	50	0.07		

On comparing the overall effect of therapy on chief complaints, between group A and group B, Mann Whitney U value suggested that a statistically significant difference ($p < 0.05$) was found between the groups in chief complaints of tiredness with relief of 100%, in A group (GYV) whereas in group B (PBV) relief of tiredness with relief of 50%. All the other chief complaints viz. polyphagia, polydipsia, polyuria, random body pains and weight loss remained statistically insignificant in between the groups with percentage relief of 66.66, 60, 72.95, 100 and 50 respectively in group A (GYV) and 42%, 100%, 49.1%, 80.28% and 50% respectively in group B (PBV) group ($p > 0.05$)

Effect of Therapy on Biochemical parameter between the Group A (GYV) and Group B (PBV) (N=17)

Table 11: Effect of Therapy on Biochemical parameter between the groups

Biochemical parameter	**Group**	**Mean diff.**	**% Relief**	**SD±**	**'t'**	**P**
FBS	A	46.2	20.9	23.1	-0.996	0.335
	B	-12.714	-5.88	6.37		
PP_2BS	A	92.2	22.56	46.1	1.32	0.207
	B	-57	-22	28.5		
HbA_1c	A	0.71	6.78	0.355	-1.071	0.301
	B	-0.486	-5.22	0.243		
C-peptide	A	-0.0175	-0.043	0.008	-0.118	0.912
	B	0.055	27.5	0.027		

On comparing the effect of therapy between group A and group B, the unpaired t value suggested statistically insignificant difference ($p > 0.05$) in FBS, PP_2BS, HbA_1c and c-peptide. with a relief percentage of 20.9, 22.56, 6.78 and -0.043 respectively in the A group for the parameters and percentage relief of -5.88, -22, -5.22 and 27.5 in B group respectively for the parameters.

Effect of Therapy on Insulin dose between the Group A (GYV) and Group B (PBV) (N=17)

Table 12: Effect of Therapy on Insulin dose between the groups.

Insulin dose	Group	% Relief	Mean diff.	SD±	't'	P
Insulin	A	14.07	3.9	1.95	0.703	0.493
	B	8.73	2.57	1.286		

Statistically insignificant difference (p >0.05) was found between the groups in Insulin dose with a relief of 14.07% in the A group and 8.73 % in B group.

Discussion:

As the prognosis of the disease is *Yapya,* the main intention of this study was to reduce the difficulties occurring to the child as a result of regular insulin consumption such as fluctuating blood glucose levels and compromise in the quality of daily activities. The ingredients of the trial drug was having established *Pramehaharatwa.* Along with that dietary modifications and planned physical activities were advised.

In this study, the maximum number of patients, 06 (30%) were from the age group of 14-16 years and 6-9 years. 05 (25%) patients were from the age group of 10-13 years. 03 (15%) patients were from the age group of 2-5 years.

12 (60%) patients were males, and 08 (40%) patients were females The incidence of type 1 diabetes was higher in men.[ix]

Here, 85% of the patients belong to Hindu community (17 patients); 10% belong to Muslim community (2 patients) and 5% of total (1 patient) is a follower of Sikhism.

In the present study, most of the patients, 15 (75%) were pure vegetarians and the remaining 5 (25%) patients had mixed diets. There is currently no established correlation between the consumption of vegetarian or non-vegetarian diets and the onset of type 1 diabetes.

Only 3 patients (15%) were diagnosed at 1-5 year age group. 13 patients (65%) were diagnosed between 6 and 10 years of age; whereas only 4 patients (20%) were diagnosed

after 10 years of age. T1DM has a bimodal distribution- first peak at 4-6 years of age and second peak at early puberty (10-14 years).

Among 20 enrolled patients, 15 (75%) patients had body aches as well as polyphagia whereas 14 (70%) patients had weakness/tiredness, 9 (45%) patients had polydipsia and polyuria (More marked at night), only 02 (10%) had the chief complaint of weight loss**.** The clinical presentation of T1DM need not be the typical triad of symptoms as expected in T2DM (Polyphagia, Polydipsia, Polyuria).

The majority of patients (60%, or 12 individuals) were initially diagnosed with Type 1 Diabetes Mellitus (T1DM) following an episode of Diabetic Ketoacidosis (DKA), while the remaining 40% (8 individuals) did not experience a DKA episode at the time of diagnosis.

19 out of 20 patients (95%) do regularly take insulin; that is majority of the patients enrolled in this study are following the conventional method. But one patient in this study was taking Ayurvedic medications since the day of diagnosis. She was diagnosed T1DM 3 years back, is taking regular check up with their diabetologist as well as in Ayurvedic hospital. Even though they were advised to start insulin therapy at the time of diagnosis and by the doctors prior to the enrolment in this study, the patient's parents were not willing to start insulin therapy.

In this study, out of 19 patients, all were found to be using short acting insulin (100%); 17 were using long acting insulin (89.5%) and only one patient (5.3%) uses intermediate acting insulin. All the patients used the insulin in combinations only, that is either a combination of short acting and long acting insulin or a combination of short acting and intermediate acting insulin.

In the present study, out of the 19 patients, majority (47.4% or 9 patients) has to take an insulin dose of above 30 units per day; 7 patients or 36.8% takes insulin in between 11-20 units per day and only 3 patients or 15.8% uses insulin somewhere in between 21 and 30 units per day.

In the current study, 11 (55%) patients had irregular exercise; 05 (25%) had regular exercise pattern whereas 04 (20%) patients didn't had any sort of physical activities. That is almost 75% children are having a troubled regimen. As per recent researches, the impact of exercise on glucose homeostasis is influenced by the type, intensity and duration of the activity.

12 (60%) patients were habituated to *Diwaswapna* whereas only 08 (40%) patients didn't indulge in *Diwaswapna*. In the present study, 65% (13 patients) are having an anxious mental state. At the same time, none were found depressed. 35% (07 patients) were having a calm/ jolly mental state. The mental status of children were assessed by asking the parents about the behavior of child on various situations.

Jataja Prameha in Ayurveda is not an exact correlation; but somewhat similar to T1DM because *Jataja Prameha* is *Sahaja* only and no factors other than genetics is involved in it. Keeping the differences apart, the chief complaints of both these diseases are very similar. The efficacy of an intervention depends upon innumerable factors viz. quality of the drugs, method of preparation of the formulation, regularity of administering medications, *Anupana*, seasonal variations, *Agnibala* of the patient, compatibility between the patient and medicine and many more. In Group A, except polydipsia and polyuria, all other parameters have shown a statistically significant difference. Despite being statistically insignificant, in polydipsia and polyuria an improvement of 60 and 66.66% were observed. It is a well known fact that if a finding is statistically insignificant, it does not mean they are clinically insignificant. The individual variations from person to person is a thing that cannot be accurately assessed with any scales. For instance, Acharya Charaka has mentioned about *Guru Vyadhita* and *Laghu Vyadhita.* That is, a same thing creating different impacts in different individuals due to the discrepancies in their perception threshold of pain or whatsoever. It might be due to such variations that some parameters were significant statistically while others remained insignificant. The trial drug is *Deepana* in nature which might be why *Agni* of the patients were neutralized and polyphagia were reduced. When the quality of *Agni* became good in all levels viz. *Jathara*, *Bhuta* and *Dhatu* it reflected on the quality of tissues formed also that might have helped in relieving weakness and body pains. On the other hand, in Group B none of the parameters were found statistically significant despite having a 100% relief in polydipsia, 80% relief in body pains etc. It is also possible that due to lesser sample size the statistical analysis can be inaccurate at times. The intervention in the control group was placebo which helps to relieve symptoms of the patient by a complex set of interactions like conditioning, contextual cues, verbal cues, motivation etc.

In Group A, except c-peptide, all the other criterion viz. FBS, PPBS, HbA1c showed positive improvement. C-peptide is a byproduct that is formed when pancreatic beta cells produce insulin and hence is an indirect indicator of insulin producing capacity. This data implies that

no remarkable rejuvenation of beta cells took place in Group A. FBS and PPBS values are for a particular point of time whereas HbA1c is the average glycemic status for 3 months. Suppose if the child follows all the instructions regarding diet and regimen for some days prior to the anticipated investigation dates also, it can bring changes on FBS, PPBS values. But only if the glycemic control is stable throughout the whole period only a change occurs in glycosylated Hb. In T1DM patients wide range fluctuations of blood glucose is observed that is, at one point of time the patient is hypoglycemic and after some time they may be hyperglycemic. Hence the authenticity of HbA1c in a disease like T1DM should be further looked into and so are the role of other objective parameters. As there are no finer options at the current scenario to accurately assess T1DM there are no options other than relying upon objective parameters. But undoubtedly it will be inappropriate if a physician's assessment of the patient is completely based upon their laboratory findings.

Another important point of concern is that in various patients amidst the intervention period, their consultant diabetologist reduced the insulin dose. The abrupt reduction of insulin dose prior to being properly acquainted with Ayurvedic medications might have altered the homeostasis the child has developed over time. This might be another reason for not showing a good range of improvement or a statistically significant difference in Group A.

In Group B, all parameters except c-peptide showed a negative range of deviation. Group B, the control group used placebo as intervention, which is presumed to be neutral and the impacts that a placebo can create is the output of a complex set of neuropsychiatric interactions. The placebo used in this study was made up of plain roasted semolina seeds which has been previously used in various T2DM trials as control.[x] Here, c-peptide showed a positive range of difference, which indicates improvement in pancreatic beta cell activity, but it might be transient too, as in honeymoon phase. Worsening status of all other parameters can be interpreted in 2 ways: Either the child indulged in careless diet and regimen or the patient was not at all convinced by the medication which again can occur due to innumerable causes (eg. The negative opinion of one of the close family relative might have changed the perception regarding the medication on their mind/ an episode of infection major or minor in between the treatment course that might have altered the glycemic balance).

A significant reduction in insulin dose was observed in both groups with a reduction of 14.07% and 8.73% respectively. GYV had all ingredients with proven anti diabetic, anti

inflammatory and anti oxidant properties as already discussed in the drug review section. This might have caused the increase in glucose utilization by the tissues. Besides, the ingredients are *Laghu, Ruksha, Katu, Tikta* which might have absorbed the excessive *Kleda* and so formed *Malas* in the body improving the quality of *Agni* thereby stimulating glucose uptake and utilization.

In Group B, there was a statistically insignificant change in insulin dose reduction ($p>0.05$) despite having a reduction percentage of 8.73%. Even if the intervention in this group had no medicinal properties, such a percentage reduction in insulin dosage was found which might most probably be due to the honeymoon phase of the disease which naturally make the remnant pancreatic beta cells to be more functional and hence producing more amount of endogenous insulin or due to a complex neuropsychiatric interaction in the patient's brain by his strong belief in the efficacy of medicine.

Conclusion:

Considering the observations and analysis of this clinical trial, it can be concluded that alternate hypothesis (H_1) is rejected and null hypothesis (H_0) **"*Gayatriadi Yoga Vati* as an add on intervention is not effective in the management of Juvenile Diabetes"**

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