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A clinical study to evaluate the effect of green tea in the patients of diabetes mellitus

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Abstract

Background: Diabetes Mellitus has emerged as an important public health problem globally. According to International Diabetes Federation, 61.3 million people in India had diabetes in 2011. That figure is projected to rise to 101.2 million by 2030 which is proving to be a major health problem. Prameha (Madhumeha) is a atipravriti janya mutra vikara. Aushadhi Sevana Kala plays an important role in the success of treatment. Tea is the most consumed drink in the world after water. Catechins and polysaccharides in green tea have been shown to lower blood sugar. Hence Green tea is selected for the present study which is thought to be effective in reducing post prandial blood sugar and also averts long-term complications.

Methods: The cases of Madhumeha were collected from OPD and IPD of Kayachikitsa, Department of parul university, limda, waghodiya Vadodara, Gujarat Study conducted by screening, enrolment & follow up visits every 7 days till 28 days where in subjective, objective & lab parameters. The medication processed green tea capsules was given in the case of madhumeha with respect to time of administration using randomization and not disturbing the patient's ongoing treatment protocol. The results obtained were methodically analyzed and statistical analysis will be done using Annova test.

Results: Looking into the Glycemic parameter Green tea showed a better reduction on PPBS. In Group B (with meal) there was mean reduction in PPBS from 235.6 to 223.7 i.e 11.9 mg/dl. In Group C (30 minute after meal) there was mean reduction in PPBS from 240.8 to 218.1 i.e 22.7 mg/dl. By observing above result of Group B & C, Even though it was statistically non-significant, we can assumed that green tea having role in reducing PPBS. The cause being short duration of the therapy & Small Sample Size

Conclusion: There was no significant reduction of PPBS by Green Tea with respective to time of administration. But still however there was reduction in mean with meals (11.9) and after meals (22.7) with respect to time administration of green tea.

Keywords: Madhumeha, green tea, diabetes, catechin

Introduction

Diabetes Mellitus has emerged as an important public health problem globally. Diabetes Mellitus is a metabolic disorder characterized by hyperglycaemia due to deficiency or diminished activity of insulin. According to International Diabetes Federation, 61.3 million people in India had Diabetes in 2011^[1]. That figure is projected to rise to 101.2 million by 2030 which is proving to be a major health problem^[2]. Ayurveda emphasis to follow the rules & regimes of Dinacharya, Ratricharya, Ritucharya Sadvrutta etc to maintain and promote the health, because of globalization, industrialization metabolic disorders such as Diabetes Mellitus, Obesity, Metabolic syndrome etc, have emerged as major life threatening condition in young population. Prameha (Madhumeha) is a mutravaha srotogata vikara^[3]. Prameha is an atipravriti janya mutra vikara. Madhumeha which is supposed to be one of the Asthamaha gada is subtype of vataja Prameha. Aushadhi Sevana Kala plays an important role in the success of treatment^[4]. Large prospective studies reveal two-hour post-meal hyperglycemias to be indicative of high risk for cardiovascular mortality⁴. Tea is the most consumed drink in the world after water^[5]. Green tea is a 'non-fermented' tea and contains more Catechins than black tea or oolong tea^[6]. Catechins are *in vitro* and *in vivo* strong antioxidants. Green tea has been extensively studied in people, animals and laboratory experiments^[7]. Additionally, Catechins and polysaccharides in green tea have been shown to lower blood sugar.

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Materials & Method**Clinical study**

Source of data: OPD and IPD of Kayachikitsa department of parul Ayurved Hospital

Study design: A randomized controlled clinical trial

Study participants: Patients suffering from Type 2 diabetes mellitus

Sample size: 30 **Follow up during treatment period:** At interval of 7 days for a period of 28 days.

Inclusion criteria

1. Known case of type 2 diabetes mellitus.
2. Patients between the age group of 30 to 70 years of either sex.
3. On stable Anti Diabetic Treatment for at least 3 week.

Exclusion criteria

1. Type 1 Diabetes Mellitus.
2. Any major concomitant illness or hospitalization for Myocardial Infarction, Cardiovascular disease, Renal, Gastrointestinal disease (especially - Chronic Intestinal disease, Irritable Bowel Disease, Intestinal Ulceration) carcinoma, HIV, Tuberculosis etc; Stroke or surgery within 2 months from screening.
3. Pregnant & Lactating women.
4. Had participated in any clinical trial within 3 months of screening.

Intervention

During the first two visits the trial subjects (processed green tea capsule) of all three groups will be advised a standard diabetic diet along with placebo capsule (wheat flour powder) was given and during the subsequent two visits the trial drug were given to the patients. And intervention was not disturb the patient's ongoing treatment protocol without up titration.

Assessment parameters

- Fasting blood sugar levels (FBS).
- Fasting urine sugar levels (FUS).
- Post-prandial blood sugar levels (PPBS).
- Post-prandial urine sugar levels (PPUS).

Study Details

Total patients registered for the study: 33 Completed: 30 Drop outs: 3 Of the 33 patients selected, 3 patients dropped out allocated intervention as they failed to attend study visit because of work commitments or moving out of the area. One subject with poor blood sugar control (fasting plasma glucose values ≥ 450 mg/dL) at 7th day was excluded as considered the risk of hyperglycemic hyperosmolar nonketotic coma. The rest of the subjects completed the study according to the approved research protocol.

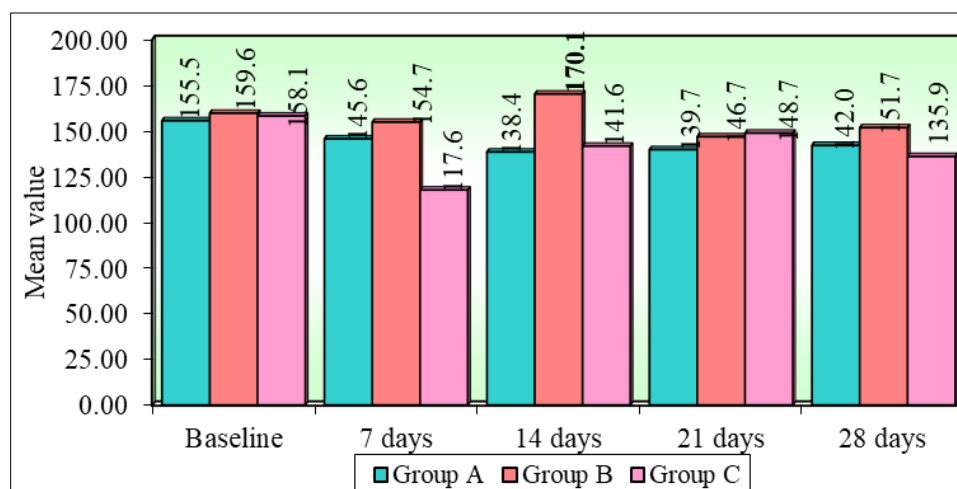
Result

Table 1: Comparison of three study groups (A, B, C) with FBS scores at baseline, 7 days, 14 days, 21 days and 28 days by one way ANOVA

Groups	Baseline		7 days		14 days		21 days		28 days	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group A	155.5	40.9	145.6	43.5	138.4	46.4	139.7	50.6	142.0	52.6
Group B	159.6	35.7	154.7	43.7	170.1	57.4	146.7	57.6	151.7	52.4
Group C	158.1	1063	117.6	60.3	141.6	39.4	148.7	45.3	135.9	30.9
P-value	0.9921		0.2010		0.2874		0.9193		0.7474	

Pair wise comparisons by Tukeys multiple posthoc procedures					
Grp A vs Grp B	p=0.9916	p=0.9161	p=0.3218	p=0.9504	p=0.8873
Grp A vs Grp C	p=0.9963	p=0.4013	p=0.9881	p=0.9194	p=0.9537
Grp B vs Grp C	p=0.9987	p=0.2095	p=0.3968	p=0.9959	p=0.7299

There was no significant change in reduction of FBS observed in all three groups.



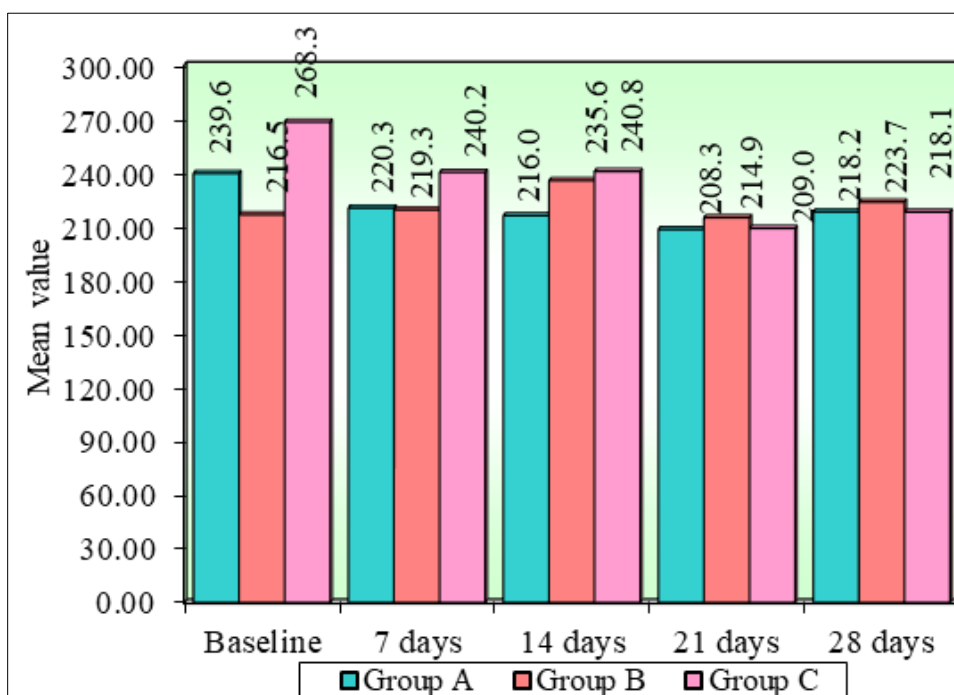
Graph 1: Comparison Of Three Study Groups (A, B, C) With FBS Scores At Baseline, 7 Days, 14 Days, 21 Days And 28 Days By One Way ANOVA

Table 2: Comparison Of Three Study Groups (A, B, C) With PPBS Scores At Baseline, 7 Days, 14 Days, 21 Days And 28 Days By One Way ANOVA

Groups	Baseline		7 days		14 days		21 days		28 days	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group A	239.6	86.6	220.3	85.6	216.0	96.8	208.3	87.7	218.2	81.6
Group B	216.5	48.7	219.3	62.4	235.6	82.8	214.9	85.0	223.7	113.8
Group C	268.3	122.2	240.2	78.8	240.8	85.7	209.0	66.4	218.1	63.0
P-value	0.4533		0.7889		0.8058		0.9798		0.9870	

Pair wise comparisons by Tukeys multiple posthoc procedures					
Grp A vs Grp B	p=0.8381	p=0.9996	p=0.8746	p=0.9816	p=0.9895
Grp A vs Grp C	p=0.7622	p=0.8300	p=0.8075	p=0.9998	P=1.0000
Grp B vs Grp C	p=0.4217	p=0.8143	p=0.9906	p=0.9853	p=0.9892

There was no significant change ($p < 0.05$) in reduction of PPBS observed. Meanwhile mean reduction observed in green tea administration period from 14th day to 21th day in all three group



Graph 3: Comparison Of Three Study Groups (A, B, C) With PPBS Scores At Baseline, 7 Days, 14 Days, 21 Days And 28 Days By One Way ANOVA

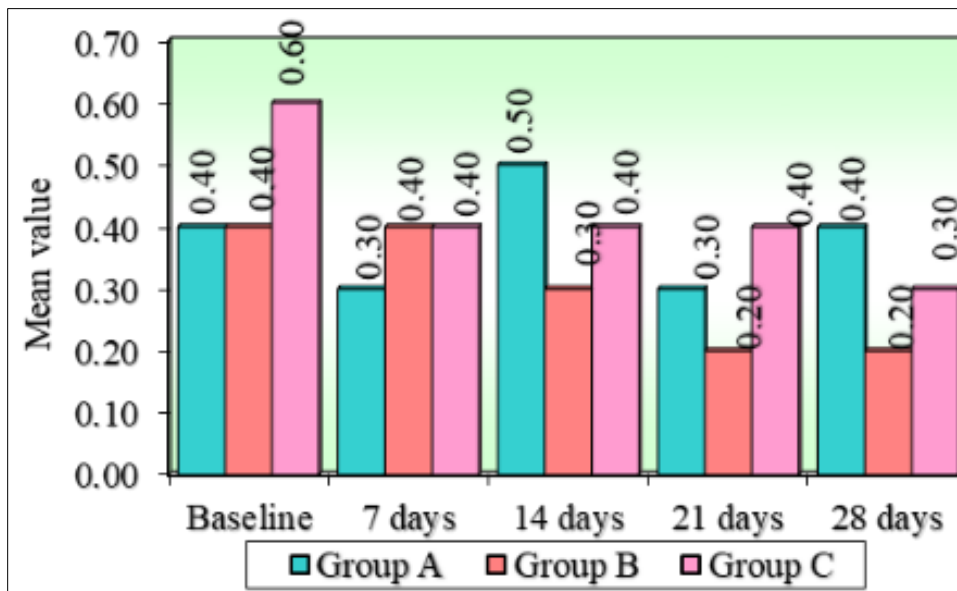
Table 3: Comparison Of Three Study Groups (A, B, C) With FUS Scores At Baseline, 7 Days, 14 Days, 21 Days And 28 Days By Kruskal Wallis ANOVA

Groups	Baseline		7 days		14 days		21 days		28 days	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group A	0.4	0.4	0.3	0.3	0.5	0.5	0.3	0.5	0.4	0.5
Group B	0.4	0.5	0.4	0.4	0.3	0.4	0.2	0.3	0.2	0.3
Group C	0.6	0.6	0.4	0.5	0.4	0.5	0.4	0.5	0.3	0.4
P-value	0.5460		0.9170		0.5700		0.5910		0.7810	

Pair wise comparisons by Mann-Whitney U test					
Grp A vs Grp B	p=0.9097	p=0.8501	p=0.3258	p=0.6232	p=0.5708
Grp A vs Grp C	p=0.4057	p=0.7055	p=0.7624	p=0.7913	p=0.6776
Grp B vs Grp C	p=0.3644	p=0.8501	p=0.5967	p=0.4057	p=0.9097

* $p < 0.05$

There was no significant change in reduction of FUS observed throughout the study.



Graph 3: Comparison Of Three Study Groups (A, B, C) With FUS Scores At Baseline, 7 Days, 14 Days, 21 Days And 28 Days By Kruskal Wallis ANOVA

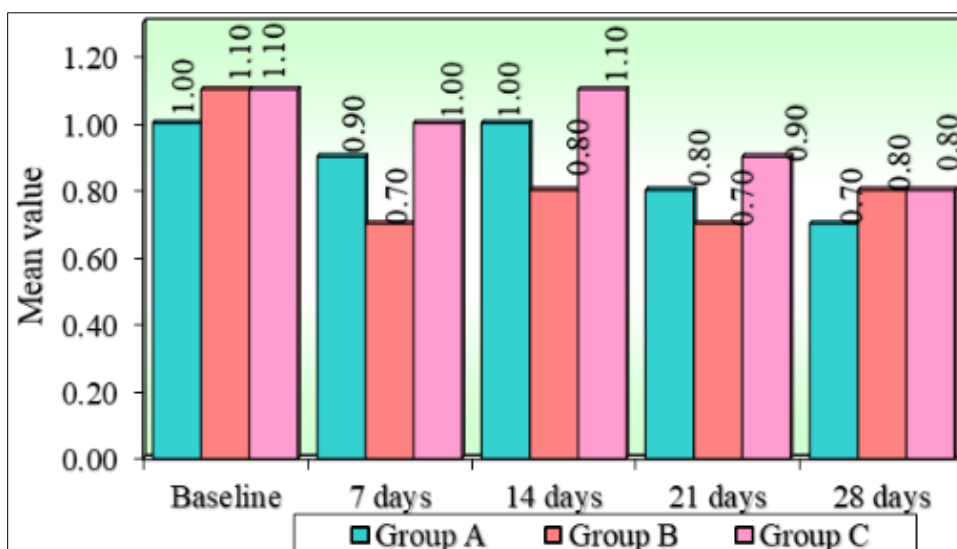
Table 4: Comparison Of Three Study Groups (A, B, C) With PPUS Scores At Baseline, 7 Days, 14 Days, 21 Days And 28 Days By Kruskal Wallis Anova

Groups	Baseline		7 days		14 days		21 days		28 days	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group A	1.0	0.4	0.9	0.6	1.0	0.6	0.8	0.6	0.7	0.7
Group B	1.1	0.7	0.7	0.6	0.8	0.8	0.7	0.6	0.8	0.5
Group C	1.1	0.7	1.0	0.5	1.1	0.7	0.9	0.5	0.8	0.5
P-value	0.8040		0.4810		0.6520		0.7670		0.7900	

Pair wise comparisons by Mann-Whitney U test					
Grp A vs Grp B	p=0.5967	p=0.5205	p=0.7055	p=0.7055	p=0.5708
Grp A vs Grp C	p=0.5708	p=0.5708	p=0.5967	p=0.7337	p=0.5708
Grp B vs Grp C	p=0.9397	p=0.2568	p=0.3847	p=0.5205	p=0.9999

*p<0.05

There was no significant change from baseline to 28th day in all three group



Graph 4: Comparison Of Three Study Groups (A, B, C) With PPUS Scores At Baseline, 7 Days, 14 Days, 21 Days And 28 Days By Kruskal Wallis Anova

Discussion on Clinical Outcome

Green tea has been used traditionally to control blood sugar in the body. Animal studies suggest that green tea increased the basal and insulin stimulated glucose uptake of rat

adipocytes [8]. In addition EGCG exhibited anti diabetic properties by suppressing gluconeogenesis in rat hepatom [9]. Epidemiologically, it has been suggested that green tea consumption prevents type 2 Diabetes [10]. The present study

was to evaluate the effect of green tea on Post Prandial Blood Sugar. The Previous studies have also shown the efficacy of green tea in hyperglycemia^[11, 12]. Looking into the Glycemic parameter Green tea showed a better reduction on PPBS. In Group B (with meal) there was mean reduction in PPBS from 235.6 to 223.7 i.e. 11.9 mg/dl. In Group C (30 minute after meal) there was mean reduction in PPBS from 240.8 to 218.1 i.e. 22.7 mg/dl. By observing above result of Group B & C, Even though it was statistically non-significant, we can assume that green tea having role in reducing PPBS. The probable mode of action of green tea in this regard maybe due to the properties like Kleda Vahana, Grahi, Mridu Uttejaka, Swedala Mutrala and Nidra Nashaka^[13]. The Kleda Vahana occurs through the Mutrala action in this Kleda Pradhana Vyadhi. The Uttejaka Karma helps in the Alasya and Asya Sukha is one of the prime nidaana of Madhumeha. The Nidranashaka Guna of this drug dose takes care of the Atinidrata or Diwaswapna which is one of the highlighted nidaana in the prameha as Swapna Sukha. The probable cause for non-significant result may be due to, Short duration of therapy, Small Sample Size, Variations in the bioavailability and metabolism of catechins in humans Digestive enzyme present in gut micro flora plays a major role in the absorption of polyphenols present in Green Tea^[14]. Green tea widely consumed in the form of tea leaves. In present study GT leaves were powdered & in the form of capsule in the dose of 1 gm t.i.d was administered the amount of catechins also varies in the original tea leaves (variety, origin, growing conditions, etc.) both quantitatively and qualitatively; The preparation of fresh green powder cannot totally extract catechin from the leaves. EGCG - are not readily absorbed^[15], with small percentages of orally ingested catechins. The patients in whom PPBS level was not decreased. This may be one of the reason.

Conclusion

There was no significant reduction of PPBS by Green Tea with irrespective to time of administration. But still however there was reduction in mean with meals (11.9) and after meals (22.7) with respect to time administration of Green Tea.

Scope for further study

Future studies with larger numbers of patients will be required to investigate the clinical characteristics of patients with a better response to Green tea. A similar study, with prolong duration of therapy can be performed, to get significant results in post prandial blood sugar.

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