Research Paper

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Effect of *Syzygium Cumini* (Jamun) Seed Powder on Blood Pressure in Patients With Type 2 Diabetes Mellitus - A Double Blind Randomized Control Trial.

Medical Science

KEYWORDS : Type 2 diabetes mellitus, Syzygium cumini, seed powder, blood pressure.

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ABSTRACT

BACKGROUND: Hypertension is a common comorbidity in patients with type 2 DM, contributing to morbidity and mortality associated with disease, demanding control of both hyperglycemia and hypertension. Antihyperglycemic effect of Syzygium cumini seed powder is proved by many studies, but not sufficient data till date available for its antihypertensive effect, which should also be brought into light.

AIMS AND OBJECTIVES: To study effect of jamun seed powder on blood pressure in type 2 diabetes mellitus.

MATERIAL AND METHODS: Patients with type 2 DM (n=99) were randomly divided in two groups- group A (n=50) was supplemented with 10 gms/day jamun seed powder and group B (n=49) was given placebo powder. Patients and investigators were blinded about treatment allocated. S.B.P. and D.B.P. were noted at baseline and 30th, 60th and 90th day. All the data was collected and analyzed at the end of study.

STATATISTICAL ANALYSIS: critical difference was calculated using one way ANOVA through INDOSTAT software and two groups were compared using t-test through MSTAT software.

OBSERVATIONS AND RESULTS: It was observed that mean S.B.P. of group A reduced significantly from 152±17.14mmHg to 145±15.47mmHg, 143±14.41mmHg and 140±13.23mmHg after supplementation with jamun seed powder for 30, 60 and 90 days respectively. Mean D.B.P. of group A reduced significantly from 91±13.57mmHg to 86±11.60mmHg and 85±3.91mmHg after 60 and 90 days respectively. No significant change was observed in S.B.P. and D.B.P. of group B.

CONCLUSION: Supplementation with jamun seed powder significantly lowers the blood pressure of patients with type 2 diabetes mellitus besides its known antihyperglycemic effects. Thus it help in improving overall health of diabetic patients. However, before recommendation multicentric trial with larger sample size, dose and duration should be planned.

INTRODUCTION

Hypertension may be clinically defined as that level of blood pressure at which the institution of therapy reduces blood pressure–related morbidity and mortality. A recent classification recommends blood pressure criteria for defining normal blood pressure as S.B.P./D.B.P. <120/80 , pre hypertension as S.B.P./D.B.P. : 120-139/80-89 , hypertension stage I as S.B.P./D.B.P.: 140-159/90-99 , hypertension stage II as S.B.P./D.B.P. ≥160/100, and isolated systolic hypertension as S.B.P. ≥140 and D.B.P. <90:, which is frequent among the elderly.[1]

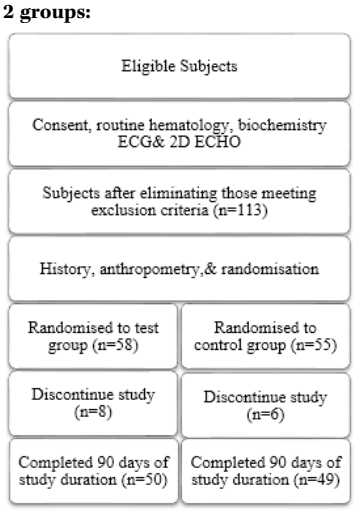
Prevalence of hypertension is ~1.5-2.0 times greater in patients with DM than in an appropriately matched nondiabetic population. Mechanism, onset and prevalence of hypertension differ in type 1 DM and type 2 DM patients with type 1 DM generally do-not present with hypertension at the time of diagnosis. Blood pressure rises after the onset of renal insufficiency and hypertension then exacerbate the progression to end-stage renal failure type 2 diabetes mellitus patients are usually hypertensive at the time of diagnosis. Many factors contribute to hypertension in type 2 diabetes mellitus such as obesity, advanced age of diagnosis and renal insufficiency at the time of diagnosis. Hyperglycemia in diabetic patients increases total body exchangeable sodium may lead to extracellular fluid accumulation and expansion of the plasma volume. It has also been suggested that hyperinsulinemia and insulin resistance may also contribute to the maintenance of hypertension because of promotion of sodium retention and enhancement of sympathetic nervous system activity.[2]

Chronic hypertension may lead to many adverse effects on major organ systems in body[3], necessitating its effective control. Many patients of type 2 diabetes are dually diagnosed as hypertensive and diabetics from the beginning and hyperglycemia in type 2 diabetes patients contributes to development of hypertension, treatment of hyperglycemia might produce beneficial effect on hypertension. *Syzygium cumini* (jamun) of the family Myrtaceae has been widely used to treat diabetes by the traditional practitioners over many centuries.[4] Its anti-hyperglycemic effects have now been proven in many studies.[5-9] Thus we should find out its effect on lowering blood pressure in addition to glycemic control, keeping in mind interrelation of hyperglycemia and hypertension.

MATERIAL AND METHODS:

Study design was single centered, double blind, randomized controlled parallel designed trial. The study was carried out in accordance with the declaration of Helsinki (2000) of the World Medical Association and approved by the local medical ethics committee. Before enrollment, details about nature and utility of study were explained to all patients and informed consent was taken. Study included a total of 99 patients with type 2 diabetes mellitus with poorly controlled blood sugar levels, F.P.G. >126 mg/dl and post prandial blood sugar >180 mg/dl during continued treatment with oral hypoglycemic agents. Patients with with sepsis, malignancy or terminally ill patients, cerebrovascular, liver disease or renal failure were excluded from study to avoid any unknown serious side effects. Pregnant patients were also excluded to avoid, if any, harmful effect on fetus.

Patients included in study were randomized and assigned to 2 groups:



Subjects in test group (Group A) were given S.cumini seed powder in a dose of 5 gms twice daily before meal, a total of 10 gms per day and subjects in control (Group B) group were given placebo powder Baseline S.B.P. and D.B.P. was noted repeat measurement was taken on 30th, 60th, 90th day. Patients and all investigators were blinded to the treatment assigned throughout the study. Patients were advised to report any adverse reactions to treating physician in charge of patients. Treatment allocated was enclosed in sealed envelope to which physician in charge of patients had access to only in case of an emergency.

RESULTS:

TABLE 1:

Mean S.B.P.(mm Hg) of test group and control group:

	Day 0	Day 30	Day 60	Day 90	CD##
Group I (test) (n=50)	152±17.14	145±15.47	143±14.41	140±13.23	5.96
Group II (control) (n=49)	139±16.53	138±15.58	138±13.95	138±13.75	6.97
Percent change in Group I		↓4.83	↓6.29	↓8.57	
Percent change in Group II		↓0.72	↓0.72	↓0.72	
t-value	3.85	2.25	1.75	1.017	
p-value#	0.0001	0.026	0.083	0.311	

Table 1 shows that, mean S.B.P. in test group was 152±17.14mmHg and in control group was 139±16.53mmHg on day 0 ($p<0.05$), after 60 days of supplementation with *S.cumini* seed powder mean S.B.P. in test group was 143±14.41 mmHg and in control group was 138±13.95 mmHg ($p>0.05$). There was statistically significant difference between two groups at the beginning of study, mean S.B.P. of group B being lower than group A, which became non-significant after supplementation with *S.cumini* seed powder.

During analysis of test group it was observed that mean S.B.P. was decreased by 4.83% (absolute reduction of 7mmHg) after receiving supplementation with jamun seed powder for 30 days, which was found to be more than critical difference of 5.96 mmHg (minimum value required to be achieved to be considered as statistically significant). There was progressive improvement in S.B.P., which decreased by 6.29 % and 8.57% after 60 and 90 days of supplementation respectively.

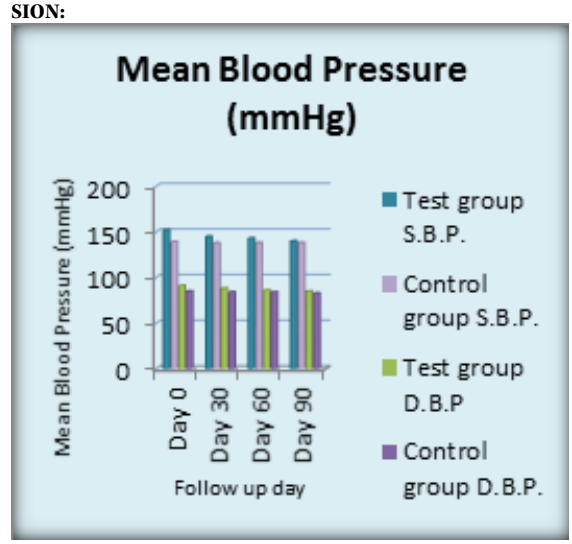
TABLE 2:

Mean D.B.P. (mm Hg) of test group and control:

	Day 0	Day 30	Day 60	Day 90	CD##
Group I (test) (n=50)	91±13.57	88±12.58	86±11.60	85±3.91	4.78
Group II (control) (n=49)	85±10.67	84±10.20	84±9.73	83±9.73	4.02
Percent change in Group I		↓3.41	↓5.81	↓7.06	
Percent change in Group II		↓1.19	↓1.19	↓2.41	
t-value	2.44	1.73	0.92	1.34	
p-value#	0.016	0.086	0.359	0.183	

Table 2 shows that Baseline D.B.P. was significantly different in two groups ($p<0.05$), higher in test group 91±13.57mmHg than control group 88 ± 12.58mmHg, which became statistically non-significant after 30 days of supplementation to test group ($p>0.05$). In group A. D.B.P. decreased by 5.81 % after 60 days, an absolute reduction of 5 mmHg, which was more than critical difference of 4.78 mmHg. Decrease in D.B.P. in group B by 1.19% after 30 days and further upto 2.41% at 90 days was less than critical difference of 4.02mmHg, so was statistically non-significant.

Figure 1: Graph showing change in blood pressure. DISCUSSION:



Hypertension is a common problem in patients of type 2 DM. Raised blood pressure leads to damage to various organ systems in our body, thus contribute to increased morbidity and mortality. Hence control of hypertension along with hyperglycemia is essential. Lowering blood pressure with use of *Syzygium cumini* seed powder with known antihyperglycemic effects decreases overall drug burden without additional side effects.

Antihypertensive effect of *Syzygium cumini* was noticed in preclinical study by Edla de A Herculano, Cintia DF da Costa et al[10] on non-anesthetized rats, they observed that hydroalcohol extract from the fruits of *Syzygium cumini* in doses of 0.5; 1; 5; 10; 20 and 30 mg/kg induced reduction in mean arterial pressure by -15±1, -14±1, -15±1, -13±1, -11±1 and -13±2% respectively. Single oral administration of the extract reduced significant mean arterial pressure. In their study they demonstrated that the edible fruit extract of *S.cumini* contains phenolic acids (malic, gallic, caffeic and ferulic acids) which promotes hypotensive effects due to a decrease in peripheral resistance, mediated by endothelium.

In addition to above, Morton, J.[11] in 1987 mentioned that the seed extract loweres blood pressure by 34.6% and this action is attributed to the ellagic acid content.

In our study as we found that there was statistically significant reduction in average S.B.P. by 4.83%, 6.29% and 8.57 % after 30, 60 and 90 days of supplementation respectively. Mean D.B.P. decreased significantly by 5.81% and 7.06% after 60 and 90 days of *S.cumini* supplementations respectively.

Thus, jamun seed powder significantly lowers both S.B.P. and D.B.P. of patients with type 2 diabetes mellitus besides its antihyperglycemic action. However, its effect in lowering blood pressure was not immediate and requires 30 days of supplementation to produce significant lowering of S.B.P. and 60 days of supplementation was required to lower diastolic blood pressure significantly.

CONCLUSION:

Results of present study indicated antihyperglycemic effect of *Syzygium cumini* seed powder besides its antihyperglycemic effect. Thus in future, syzyium cumini may emerge as a drug with multiple effects that improves overall health of diabetic patients and decrease morbidity and mortality associated with disease. Being cost effective it may help in health of diabetic patients in rural population.

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