

## **Efficacy of vijaysar, aloe vera alone and their combination in the treatment of newly diagnosed cases of type 2 diabetes mellitus: a randomized single blind prospective study**

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### **ABSTRACT**

**Background:** Diabetes mellitus is a disease was known since ancient time and all system of medicine over world were tried to cure this disease. Unfortunately the numbers of diabetes patients are increasing day by day due to many risk factors such as sedentary life, obesity etc.

**Methods:** A total of 120 patients with newly diagnosed type 2 diabetes mellitus attending OPD of UPUMS, Saifai, Etawah, Uttar Pradesh, India, were included in the study. Patients were divided into 4 groups. Group-1, 2, 3 and 4 received Aloe vera, Vijaysar, Aloe vera + Vijaysar and Glimpiride respectively for thirteen weeks. Sample for fasting blood sugar and postprandial blood sugar were measured at baseline, 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 5<sup>th</sup>, 8<sup>th</sup> and at 13<sup>th</sup> week. HbA1c and Lipid profile were measured at baseline and at thirteen week.

**Results:** Significant decrease in FPG, 2hPG, and HbA1c level were achieved in all groups but effects was maximum in Glimpiride group. Vijaysar had shown better glucose control than Aloe vera as well as Aloe vera + Vijaysar group. Synergism was shown by both herbal drugs for FPG control but not for 2hPG. The Effect of Vijaysar alone on 2hPG was similar to Glimpiride.

**Conclusions:** Vijaysar could be a promising herbal drug for the treatment of mild uncomplicated cases of type-2 diabetes mellitus; however both drugs have shown synergism for FPG control. Both herbal drugs were safe during our study, only one patient of Vijaysar group had complaint of diarrhoea, which was subsided one week later.

**Keywords:** Aloe vera, Diabetes mellitus, Vijaysar

### **INTRODUCTION**

Diabetes mellitus is a metabolic syndrome characterised by hyperglycaemia, dyslipidaemia, multiple organ disorder and organ failure, which impairs the quality of life and leads to comorbidities and death. Diabetes is a major lifestyle disease associated with sedentary life. It is not a single disease but a heterogeneous group of multiple disorders associated with glucose metabolism.<sup>1</sup> Number of diabetes patients is increasing day by day with approach to become pandemic. Current prevalence is more dangerous than what we expected earlier. As per study, by 2040 the prevalence of worldwide and Indian diabetic patients will be approx 642 and 123.5 million while it was 415 and 69.2 million in 2015 respectively. Diabetes prevalence in India is just second to China.<sup>2</sup>

Control measures are essential for individual patients to improve glucose homeostasis. Development of diabetes involved multiple organ but most important organs which are involved in pathogenesis are pancreas, liver and skeletal muscle. Management of diabetes includes oral hypoglycaemic medicines, diet control and life style modifications, these all are important in management of diabetes mellitus irrespective of diabetes types. Currently available medicines are efficacious in controlling of plasma sugar but these are unable to prevent the complications and progression of disease. Some of the adverse effects like hypoglycaemia, GIT disturbances limit their use. India, China and other countries have used alternative medicine for the treatment of diabetes mellitus since ancient time. WHO also promote the experiments on plants for development of newer drug. About 400

plants from various part of world are recognised for the treatment of diabetes, in which some of them were evaluated by scientifically designed studies.<sup>3</sup>

The anti-diabetic effect of some herbal preparation has been found in animal as well as in patients of type 2 diabetes. Some of these herbal preparation and associated work are mentioned bellow Vijaysar and Aloe vera both herbal drugs have anti-diabetic potency as evaluated by many researchers in animal as well as in diabetic patient.<sup>4,5</sup>

### ***Aims and objectives***

- To evaluate the anti-hyperglycemic effect of Aloe vera, Vijaysar and their concomitant use in newly diagnosed type 2 DM patients.
- To compare the anti-hyperglycemic effect of above drugs with Glimpiride
- To find out any adverse effect, if any.

### **METHODS**

#### ***Source of data***

Newly diagnosed or untreated patients with type 2 diabetes mellitus aged between 30 to 60 years were included in this study on the basis of inclusion and exclusion criteria from Medicine outpatient department (OPD) of UPUMS, Saifai Etawah. The inclusion criteria were newly diagnosed and untreated type 2 diabetes mellitus and the exclusion criteria were type 1 diabetes mellitus, insulin requirement, fasting blood glucose level >230 mg/dl, significant nephropathy with serum creatinine  $\geq 2.5$  mg/dl, patient with retinopathy and neuropathy, patient with hypertension, cardiovascular complication such as ischemic heart disease and congestive heart failure, liver disease as evaluated by abnormal level of ALT, AST and alkaline phosphatase  $\geq 2$  times of normal, pregnancy and lactation. Written informed consent obtained from each patient who was willing to participate in this study. Eligible patients were randomly allocated in one of the four groups. All patients were advised to take diabetic diet as told.

#### ***Medications***

Tablet Glimpiride was provided by hospital supply from OPD as routine process, capsule: Vijaysar-500mg and capsule: Aloe vera-300mg, these capsules were purchased from Mystic Herbal Lab Bareilly. The company prepared these capsules on special order by us.

#### ***Study design***

This study was a randomized single-blind study. The duration of drug treatment and active intervention was 13 weeks, with 1 weekly follow up in our hospital for evaluation of progress, effect of treatment and for drug collection. At the time of visit blood sample were

collected for measuring of FPG and 2h- PG g levels and adverse effects and complication of diabetes such as hypoglycaemia, neuropathy if any, were noted. If a patient developed any disease or serious side effects during this period which required active intervention of any type, he/she was to be withdrawn from this study, however no such type of case was seen in our study. All drugs were self-administered by the patients of all groups. It was told to all groups that drug has to be taken as advised. The starting daily dose was 1 capsule of Aloe vera twice a day (600 mg) to Group- 1, 2 capsule of Vijaysar twice a day (2 g) to Group-2, 1 capsule of Vijaysar twice daily (1g) and 1 capsule of Aloe vera once daily (300 mg) to Group-3 and 1 mg of Glimpiride once daily to Group-4.

#### ***Follow-up of patients***

Follow up of patient was done according to following ways. At the end of one week, if blood glucose control was not achieved, the daily dose was not changed in any group and we wait up to 4 weeks. If blood glucose was not achieved even at the end of 4th week, there was no changes were made in group 1st because maximum daily dose of Aloe vera has been prescribed. The daily dose was increased up to 3gm of Vijaysar in group 2nd if glycaemic control was not achieved, however in patients of 3rd group, the dose of Vijaysar was increased up to 2 gm while the dose of Aloe vera remain same if glycaemic control has not achieved and Glimpiride was increased up to 2mg if glycaemic control has not achieved in 4th group.

At the next visit blood glucose was assessed, if the blood glucose was under control, continue same dosage, if glycaemic control was not achieved, the dosages of drugs were increased to maximum level i.e. 4g of Vijaysar, in group 2nd, 3gm of Vijaysar 3rd group, and 2 mg of Glimpiride in 4<sup>th</sup> group.

#### ***Randomization***

Present study was single blinded study, in which only patients were unaware about the type of medication received. Randomization was done in following ways. 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> patient was enrolled in group 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> patient in 1st respectively and so on.

#### ***Laboratory Investigations***

- *Primary parameters:* Fasting Plasma Glucose (FPG) and 2h Plasma Glucose (2h PG).
- *Secondary parameters:* Glycated haemoglobin (HbA1c)

#### ***Measurement of biochemical parameters***

All biochemical tests were carried out by specific enzymatic methods as done by our institute routinely.

### Statistical analysis

The following statistical methods were applied in the present study:

- Mean  $\pm$  Standard error of mean (mean  $\pm$ SEM).
- One way analysis of variance (ANOVA) was used to examine the difference of the mean of parameters test among the studies group.

Paired t-test was used to compare the baseline and final values of blood glucose, HbA1c, and lipid profile within the group; Student's unpaired t-test was used to compare the difference in the mean changes in blood glucose, lipids and other laboratory values between the Glimperide and other groups.

In the present study p values  $<0.05$  was considered significant.

### RESULTS

During study period 140 patients were enrolled out of which 32-36 patients were randomly allocated in four groups.

The drop out were approximately 5 in each group, statistical analysis was done for 30 patients. Demographic profile of patients of all group were almost similar and have no significant difference.

The demographic profile of each group was similar (Table 1).

The baseline parameters were taken before enrolment of patients, there were no significant difference exist between baseline parameters of all groups as shown in Table 2.

**Table 1: Demographic parameters of all groups.**

Characteristics	Group-1 (n=30)	Group-2 (n=30)	Group-3 (n=30)	Group-4 (n=30)
Male (%)	50	40	43.4	53
Mean age (years)	50.57 $\pm$ 1.77	52.50 $\pm$ 1.75	52.17 $\pm$ 1.89	51.67 $\pm$ 1.71
Family history (%)	31	33	34	30
Cardinal symptoms	Polyuria	53	54	51
	Polydipsia	51	55	57
	Polyphagia	49	54	53

**Table 2: Baseline value of the FPG, 2h PG and HbA1c of all groups.**

Parameter	Group-1 Aloveera	Group-2 Vijaysar	Group-3 Aloveera+ Vijaysar	Group-4 Glimperide	p-value
FPG	155.60	155.47	153.60	153.97	0.614
2h-PG	268.63	259.10	271.53	261.80	0.425
HbA1c	7.09	7.03	6.98	7.04	0.830

**Table 3: Baseline, 13th week values and mean fall.**

Parameters	Drug groups	Baseline	At 13 <sup>th</sup> weeks	Mean fall
FPG	1 <sup>st</sup>	155.60	111.83	43.77
	2 <sup>nd</sup>	155.47	111.53	43.94
	3 <sup>rd</sup>	153.60	98.77	54.83
	4 <sup>th</sup>	153.97	81.37	72.60
2h PG	1 <sup>st</sup>	268.63	184.23	84.40
	2 <sup>nd</sup>	259.10	178.13	80.97
	3 <sup>rd</sup>	271.53	184.50	87.03
	4 <sup>th</sup>	261.80	170.17	91.63

All groups includes 30 patients, blood sample collected at baseline and at the end of 1st, 2nd, 3rd, 5th, and 8th and at 13th week for FPG and 2h PG and for other parameters like HbA1c and lipid profile, at baseline and at the 13th week. Patients of group 1<sup>st</sup> were treated by capsule Aloveera at the dose of 300 mg twice daily. Patients of

2<sup>nd</sup> group were treated by capsule of Vijaysar, initially at the dose of 1g twice daily and then dose was gradually titrated according to response. Patients of 3<sup>rd</sup> group were treated with capsule Vijaysar at the dose of 500 mg twice daily and capsule Aloveera at the dose of 300 mg once daily. The dose of Vijaysar was titrated according to glycaemic control. Patients of 4th group were treated by tablet Glimperide. (1-8 mg) once daily at the time of meal or just before meal. The dose of Glimperide was titrated according to glycaemic control.

#### Effects of treatments on FPG and 2h PG

##### Efficacy of drugs

Initially at 1st and 2nd week there were no significant reduction in all groups, however the difference between baseline and end point was continuously increased, which was maximum in group 4. Mean fall in all group is given in Table 3.

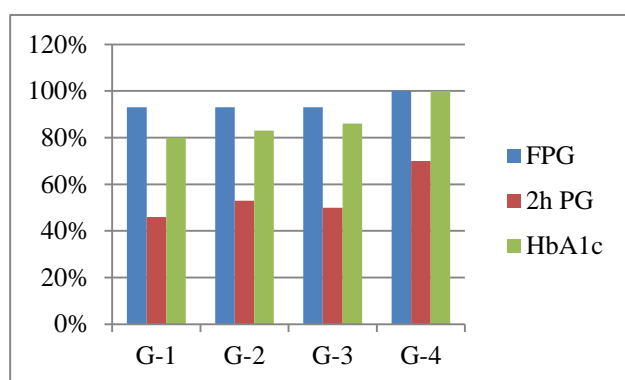
*Percentage of achievement of glycaemic control*

As shown in table and figure, all treatment groups shown control of FPG, group 1, 2 and 3 achieved FPG in 93% of patients, and group 4 achieve FPG in 100 % of patients. The control of 2h PG in the range of 46% in group 1, 53 % in group - 2, 50 % in group 3 and 70 % in group 4. (Table 4) and Figure 1.

HbA1c in all groups were well controlled by all drugs however Glimepiride had shown greater control.

**Table 4: Percentage of glycaemic control of all groups.**

Groups	FPG	2h PG	HbA1c
G-1	93%	46%	80%
G-2	93%	53%	83%
G-3	93%	50%	86%
G-4	100%	70%	100%



**Figure 1: Percentage of Glycaemic control in all groups.**

*Effect of treatment of all drugs on various parameters*

We have taken the plasma level of primary parameters at baseline, 1<sup>st</sup> week, 2<sup>nd</sup> week, 3<sup>rd</sup> week, 5<sup>th</sup> week, 8<sup>th</sup> week and at the 13<sup>th</sup> week, and secondary parameters at baseline and at 13th week.

Reason behind frequent sampling was to know whether FPG and 2h PG either increased or decreased which helped us in prevention of complications. Aloe vera, Vijaysar, and concomitant use of both drugs have shown glucose lowering effects; there were statistically significant difference between baseline values and 13<sup>th</sup> week values of all parameters in all groups.

Effects of Vijaysar on all parameters were good as glycaemic control was adequate. There were statistically significant difference found between baseline values and 13th week values of all parameters. Hypoglycaemic effect of Aloe vera and Vijaysar combination on FPG was more than Aloe vera and Vijaysar alone, while on 2h PG was more than Aloe vera, but less than Vijaysar.

*Comparison of efficacy of each group with group 4*

We compared the 13<sup>th</sup> week data of 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> group with that of 4<sup>th</sup> group.

Aloe vera is effective in lowering of FPG, 2h PG, HbA1c, but not as effective as Glimepiride. There were statistical significant differences in between Glimepiride and Aloe vera.

When group 4 was compared with group 2, the difference between FPG, HbA1c were highly significant, while the difference between 2h PG was not significant that indicate the effect of Vijaysar on 2hPG was comparable to Glimepiride.

On comparisons of 3rd group with that of 4th group, the significant difference were found in all parameters of group 4th and group 3rd, that indicate the hypoglycaemic effects of both herbal preparations were not synergistic.

**DISCUSSION**

Type 2 Diabetes Mellitus is a serious global epidemic disease that increases the risk of cardiovascular disease, renal diseases, ophthalmological complication and increase the chance of infections and hence increases the economic burden. A primary preventive measure for this disease is modification in lifestyle, while pharmacotherapy is useful but has some limitation and various side effects. Therefore, it is necessary to look for alternative therapies to reduce the consequences of this disease. Present study was designed to evaluate the anti-diabetic effects of Vijaysar, which has been mentioned in Indian medical system (Ayurveda) and evaluated by many researchers in India as well as in other countries. Present study also evaluated the hypoglycaemic effects of Aloe vera which also had been studied by many scientists. Other main objective of present study was to evaluate hypoglycaemic effect of concomitant use of Vijaysar and Aloe vera in type 2 diabetic patients. As per literature search till date, effects of concomitant use of Vijaysar and Aloe vera were never been studied. The findings of the present study have shown similarities with other studies on Vijaysar and Aloe vera with similar objectives. Hypoglycaemic effects of Aloe vera have shown in the present study, and similarities with the findings of previous studies.<sup>6-10</sup>

FPG control has been achieved in 93% patients and 2hPG in 46% in group 1 in present study. These improvement in glycaemic control which have been achieved by Aloe vera in the present study were similar with the clinical studies done by Ghannam N et. al and Yongchaiyudha S. et. al.<sup>7,10</sup> However hypoglycaemic effects of Aloe vera were less than that of Glimepiride in the present study. Another study done by Zarrintan et al concluded that the Aloe vera had no hypoglycaemic effects which are opposite to findings of our study.<sup>11</sup>

The present study has shown that Vijaysar has blood glucose lowering effect in newly diagnosed and untreated type 2 diabetic patients. According to ICMR study group Vijaysar has similar effects on FPG and 2hPG, while results of present study were not similar. Reduction in FPG and 2h PG were found in 86% of patients in their study, but present study shown that, Vijaysar has better blood glucose lowering effects on FPG as it was effective in 93% of patients (FPG < 130mg/dl) which is more than ICMR study, however Vijaysar has shown poor control on 2h PG (2hPG < 180mg/dl) which was only 53 % and it is much lower than that of ICMR study. Effect of Vijaysar on FPG confirmed that the Vijaysar has inhibitory effects on gluconeogenesis which is responsible for better control of FPG in diabetic patient, which support the finding of a study done by Pari L et al. Effect of Vijaysar on 2hPG is may be due to its beta cell regeneration power which is confirmed by different researcher.<sup>12-14</sup> When anti- diabetic effects of Vijaysar was compared with Glimperide in present study, only 2h PG glucose was comparable to Glimperide, while previous studies mentioned that all parameters of Vijaysar group was comparable to Tolbutamide, Glibenclamide, and Metformin.<sup>5,15-17</sup> Vijaysar also decreases the plasma level of HbA1c which suggest long term effects (3 months) on blood glucose. Various studies had shown that Vijaysar exerts multiple effects on glucose metabolism and lipid metabolism which are responsible for its anti-diabetic effects and prevent deleterious effect of diabetes on various organs.<sup>13,16,17</sup> The hypoglycaemic effects of Vijaysar were similar to the result of various studies done by many researchers in experimental model as well as in humans.<sup>18,19</sup>

Result of our study also support the results of a study done by A.V. Ramchandran et al. who concluded that the Vijaysar has hypoglycaemic effects.<sup>20</sup> Hypoglycemic episodes are major side effects which are produced by many oral hypoglycaemic agents but our study shown that there was no such type of episodes noted in either group. According to a study done by Yajnik et. al. about 80% of 43 patients treated with oral hypoglycemic drugs were able to reduce their doses and number of drugs when they are concomitantly treated with Vijaysar.<sup>21</sup>

The present study also established the safety aspect of the drug Vijaysar, as there were no adverse effects seen up to the doses of 4g per day. Only one patient said that he felt flatulence at 1st visit, which subsided at next week. The result of our study concluded that Vijaysar have anti-diabetic potential but additional studies will be required to substantiate our findings.

The present study was designed to see the synergistic effects of a novel combination i.e. concomitant use of Aloe vera and Vijaysar, which was not done previously by any researcher. According to result of this study Vijaysar and Aloe vera have synergistic effects on FPG and HbA1c but effect on 2h PG was more than Aloe vera but less than Vijaysar and Glimperide. This shows that probably the

effect of Vijaysar on 2hPG was antagonised by some component of Aloe vera. Both herbal drugs have antioxidant effect which is due to presence of various molecules in the preparations in earlier studies.<sup>22,23</sup>

## CONCLUSION

Vijaysar and Aloe vera both have the potency to be used as anti-diabetic drugs for type 2 DM. Both of them control FPG, 2h PG and complications associated with diabetes mellitus. Vijaysar has some additional property other than glucose lowering effects. Antioxidant effect of Vijaysar prevents the complications due to oxidative stress in diabetes. Non enzymatic glycation of macromolecules (proteins) are responsible for multi organ defects like diabetic nephropathy, retinopathy, neuropathy, etc. Antiglycation property of Vijaysar prevents these complications on chronic administration. Vijaysar may be used in type 1 DM along with insulin as supportive therapy, because it has  $\beta$ - cell regeneration properties as found by many researches in their studies. (-) -Epicatechin has  $\beta$ - cell regeneration properties it is found in bark of Vijaysar. If this molecule can synthesise, it can be used in type 1 DM. Concomitant use of Aloe vera and Vijaysar may be useful for lowering FPG. However this combination may antagonise the effects on 2hPG.

Further study will be required to evaluate the effects of this novel combination. On the basis of this study synergistic effect could not be denied because some molecules of Aloe vera may have synergistic effects with some molecule, but to evaluate these effects further studies required where diet control is strictly adhered and intake of drugs are supervised, preferably in indoor patients and for longer duration.

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