Brief Communication

Acarbose improves glycemic control as add-on or monotherapy in Indian type-2 diabetes: Findings from the GlucoVIP multinational observational study

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ABSTRACT

Objective: To investigate the efficacy and tolerability of the anti-diabetic agent acarbose (Glucobay®) as add-on or monotherapy in a range of patients with type-2 diabetes mellitus (T2DM), including those with cardiovascular morbidities in India. **Materials and Methods:** This was a part of a prospective, non-interventional, non-controlled, multicentre, multinational, observational study. The study included patients of either gender if they were aged at least 18 years and had untreated or pre-treated type-2 diabetes mellitus (T2DM) or impaired glucose tolerance and no acarbose treatment within the 3 months before study inclusion. **Results:** In total, 1996 Indian patients were included in the effectiveness and 2010 in the safety analysis. Patients received acarbose (25-150 mg/day). The mean age of the patients was 50.1 years and the mean BMI was 27.2 kg/m^2. Mean 2-h post-prandial plasma glucose (PPG) value and fasting blood glucose (FBG) decreased from 243.9 to 169.5 mg/dl and 158.3 to 120.4 mg/dl, respectively after the last follow-up of 12.4 weeks. The mean HbA1c value at initial visit was 8.4% and was 7.4% at the last follow-up visit. FBG, PPG and HbA1c deceased in 90.6%, 94.4% and 52.4% patients respectively, by the last follow-up visit. The mean decrease in weight and waist circumference was 1.4 kg and 1.6 cm, respectively by the last follow-up visit. Physicians assessed the efficacy of drug as positive response in "very good to good" in 91.08%, "sufficient" in 7.92% and "insufficient" in 0.90% of patients. Also, continuation of Acarbose was reported in 97.09% of patients. Adverse events were reported in 2.74% and drug-related adverse events were reported in 2.19% of patients. Majority of them were gastrointestinal adverse events but were not serious. **Conclusion:** Acarbose is effective and safe in Indian patients with T2DM. Further, it helps in weight reduction and has very good compliance in patients with T2DM.

Key words: Acarbose, alpha glucosidase inhibitor, FBG, HbA1c, India, PPG, type-2 diabetes

Introduction

Diabetes is among the most challenging health problems of 21st century. According to prevalence estimation of the International Diabetes Federation, 366 million people had diabetes in 2011; by 2030 this may rise to 552 million.[1] It has been estimated that 20% of global burden resides in South Eastern Asia Region, which will be tripled to 228 million by the year 2025 from the current 84 million.[2] India along with China will account for nearly a third of the estimated 300 million adult diabetics by the year 2025.[3]

Prospective randomized controlled studies such as the Diabetes Prevention Program (DPP) in the USA,[4] the Finnish Diabetes Prevention Study[5] (DPS), the Da Qing impaired glucose tolerance (IGT) and Diabetes Study in China[6] and the Malmo study in Sweden[7] have shown that lifestyle modification involving diet and enhanced physical

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activity helps to delay or prevent the progression of IGT to diabetes.

There are a number of major risk factors for type-2 diabetes mellitus (T2DM). Although some diabetic risks factors may be genetic, many are preventable. Some of the risk factors for T2DM include: Obesity, sedentary lifestyle and eating habits. The higher carbohydrate in the Indian and Chinese diets lead to greater prandial glycemic excursion, increased glucosidase and incretin activity in the gut and may need special therapeutic strategies to tackle these glucose peaks. Thus, a typical Indian Chinese post-meal glucose curve has wider glycemic excursion as well as greater post-prandial load which leads to lipemic peaks and has epidemiological links to cardiovascular disease.[8] There is a need of therapeutic agents that target the early stages of T2DM, such as the α-glucosidase enzyme inhibitors like acarbose, which reduces post-prandial hyperglycemia and hyperinsulinemia and increases glucagon-like peptide-1 (GLP-1),[9] may have a more prominent role to play in diabetes in such settings. In an Indian setting the role of alpha glucosidase inhibitors like acarbose is even more significant as our meal component is carbohydrate rich.[10]

Alpha glucosidase inhibitors (AGIs) belong to the class of oral anti-diabetics that reduces or delays carbohydrate digestion by competitive enzyme inhibition without causing any proactive stimulation of insulin release. Thus, they prevent post-prandial increase in blood glucose without causing hypoglycemia.[11] It has been reported that acarbose helps in the reduction of cardiovascular risk.[12] Among AGIs, acarbose is a commonly used drug, is shown to control post-prandial hyperglycemic spikes and is safe and well tolerated too.[13] Acarbose was found to be only minimally absorbed (<2%) in unchanged form. As it acts locally within the gastro-intestinal (GI) tract, this low systemic bioavailability is therapeutically desired. Hence, it is advisable to administer the same with meals.[14]

Acarbose belongs to the group of non-insulinotropic oral anti-diabetic agents. It plays an essential and direct role in carbohydrate uptake from food into the blood, but also has an indirect role in the optimization of glucose metabolism over the whole day, as it contributes to the adaptation of insulin secretion.[15]

The objective of the present study (GlucoVIP; diabetes treatment by Glucobay® with a special therapeutic view to chosen patient groups) was to investigate the efficacy and safety of acarbose (Glucobay® [Bayer AG, Berlin, Germany]) in a large multinational study, which included patients with T2DM with and without cardiovascular co-morbidities in a real clinical setting. In this study, data for Indian population has been discussed.

Materials and Methods

This current study was a part of a prospective, non-interventional, non-controlled, multicentre, multinational, observational study and was done to further explore the efficacy and safety of acarbose (Glucobay®) in a large sample of patients with T2DM under daily-life treatment conditions.[16] The study was conducted at 790 centers in 15 countries or regions (Algeria, Bosnia and Herzegovina, Cambodia, China, Hong Kong, India, Indonesia, Malaysia, Pakistan, the Philippines, Russia, Singapore, South Korea, Thailand and Vietnam) between March 2009 and December 2010. However, the current result/report discusses sub-analysis data from India. Ethics committee approval and patient written informed consent were obtained in all the countries where required by local law or regulations. The study was conducted in accordance with the ethical principles originating in the Declaration of Helsinki and with Good Clinical Practice (GCP) guidelines as far as applicable to non-interventional studies.

The study included patients of either gender with minimum age of 18 years and had untreated or pre-treated T2DM or IGT and no acarbose treatment within the 3 months before study inclusion. In Indian scenario, investigators could enroll patients with diabetes or IGT. Patients who took at least one dose of acarbose were valid for inclusion in the safety population, and patients who had at least one follow-up visit and at least two measurements of post-prandial plasma glucose (PPG) and fasting plasma glucose (FPG) were valid for inclusion in the efficacy population. The final visit was defined as the last visit recorded by the physician for that patient. Patients were excluded if acarbose treatment was contraindicated according to summary of product characteristics.

Due to the non-interventional study design, there were no additional diagnostic or monitoring procedures and no allocation of patients to treatment. Accordingly the doctor had to decide whether the said patient was newly diagnosed or not. Patients were assessed at the initial visit, when acarbose was prescribed and at up to three follow-up visits by their treating physician at any time over a period of up to 3 months. The physician decided on the follow-up times for each patient. The whole treatment, including anti-diabetic co-medication and appropriate dose of acarbose, was decided by the physician and could be adjusted at follow-up visits, according to medical practice.

Outcome measures

The 2-h PPG, HbA1c and FBG were recorded at each visit according to the physician's normal procedures. Patient's weight and waist circumference were recorded at initial and at follow-up visits. Physicians were also asked to provide a final assessment of acarbose efficacy and tolerability in each patient on a four-point scale: 'Very good', 'good', 'sufficient' or 'insufficient'. No description of the categories was provided, and the ratings were based on the physicians' assessment alone. In addition, physicians were asked to rate their own and the patient's overall satisfaction with treatment at the final visit, using a four-point scale: 'Very satisfied', 'satisfied', 'unsatisfied' or 'very unsatisfied'.

Statistical analysis

Descriptive analysis of the data was performed using summary statistics for categorical and continuous data based on non-missing values. Missing data were not estimated or carried forward. Data were stratified according to factors such as age, sex, presence of diabetic complications, and presence of concomitant vascular, cardiovascular or cerebrovascular disease. Continuous data was presented in the manuscript as mean and standard deviation (SD). Patients who took at least one dose of acarbose were valid for inclusion in the safety population, and patients who had at least one follow-up visit and at least two measurements of PPG and FPG were valid for inclusion in the effectiveness population.

Results

Study population

In total, 1996 Indian patients were included in the effectiveness and 2010 in the safety analysis. Among 1996 Indian patients 1219 (61%) were males and 776 (39%) were females. Gender of one person was not known (missing data). The demographic and baseline characteristics of the efficacy population are summarized in Table 1. The mean (SD) age of the patients was 50.1 (10.7) years and the mean (SD) body mass index (BMI) was 27.2 (4.4) kg/m^2. About 26.5% of patients were newly diagnosed and 71.9% of patients had previous diagnosis of diabetes. Also, 73.4% of patients had specific concomitant diseases. Majority of them were diagnosed with other diabetic complications (21.9%) followed by vascular disease and congestive heart failure (CHF) (16.2%).

Table 1: Demographic data and specific concomitant diseases (*n*=1996)

Variables	*n*	Mean (SD)
Age (years)	1908	50.1 (10.7)
Weight (kg)	1972	72.7 (12.6)
Height (cm)	1996	163.5 (8.6)
BMI (kg/m^2)	1971	27.2 (4.4)
Waist (cm)	1589	93.5 (12.6)
	n	**%**
Diagnosis		
Newly diagnosed	529	26.5
Previously diagnosed	1436	71.9
Concomitant disease		
Vascular disease	302	15.1
Vascular disease+CHF	323	16.2
Cerebrovascular disease	39	1.9
Cardiovascular disease	144	7.2
Cardiovascular disease+CHF	171	8.6
Other diabetic complications	437	21.9

SD: Standard deviation, BMI: Body mass index, CHF: Congestive heart failure

Anti-diabetic medication and observation period

During the study, 44.2% (*n* = 883/1996) of patients received acarbose (25-150 mg/day; mean dose 103.6 mg) as monotherapy with no anti-diabetic co-medication. The remaining 55.8% (*n* = 1113/1996) of patients received combination therapy, with acarbose being administered with one (33.8%), two (17.6%) or more (4.5%) anti-diabetic medications. The most frequent anti-diabetic co-medications were sulfonylureas (received by 427/1996; 21.4%), biguanides (*n* = 413/1996; 20.7%), and insulin and long-acting analogues (*n* = 87/1996; 4.4%). Further, mean (SD) time until 1st, 2nd, 3rd and last follow-up visit was 4.9 (2.5), 9.2 (2.2), 13.1 (1.8), and 12.5 (2.9) weeks, respectively. At the initial visit (baseline), the majority of patients were prescribed acarbose 50 mg/day (*n* = 1094/1996; 54.8%), 100 mg/day (*n* = 504/1996; 25.3%), 25 mg/day (*n* = 228/1996; 11.4%), or 150 mg/day (*n* = 133/1996; 6.7%). By the last follow-up visit, the proportion of patients receiving acarbose 50 mg/day had decreased to 33.7% (*n* = 672), and the proportion receiving 100 mg/day, or 150 mg/day had increased to 43.8% (*n* = 874) and 14.0% (*n* = 280), respectively. Preferential time for prescribing acarbose was after the breakfast.

Effectiveness of acarbose treatment

Changes in FBG, PPG and HbA1C levels

At initial visit the mean FBG value was 158.3, SD (45.1) mg/dl which decreased to 120.4 (30.1) mg/dl. The mean (SD) 2-h PPG levels at initial visit were 243.9 (64) mg/dl which decreased to 169.5 (40.2) mg/dl by last visit [Figure 1]. 2-h-PPG was recorded in overall 90.6% patients at each visit. The mean (SD) HbA1c value at initial visit was 8.4% (1.3) and was 7.4% (0.8) at the last follow-up visit [Figure 2].

Change in weight

There was a decrease in weight during the observation period of 12 weeks. Mean (SD) weight decreased from 72.7 kg (12.6) at the initial visit to 71.3 kg (12.2) at the final visit.

Change in waist circumference

Waist circumference also showed a slight decrease during the observation period of 12.8 months. The mean (SD) waist circumference was 93.5 cm (12.6) at the initial visit and was 91.9 cm (12.3) at the final visit.

Overall assessment of acarbose treatment

Physicians assessed the efficacy of drug as "very good" in 44.5%, "good" in 46.6%, "sufficient" in 7.9% and "insufficient" in 0.9% of patients. However, physicians' assessment of tolerability of drug as "very good" in 36.7%, "good" in 51.3%, "sufficient" in 11.2% and "insufficient" in 0.5% of patients [Figures 3 and 4]. Also, continuation of Acarbose® was reported in 97.1% of patients [Table 2].

Assessment of safety

Table 3 below reports data for the patients with the treatment for emergent adverse events (AEs). It was observed that out of 2010 patients, AEs were reported only in 2.74%. One death due to pneumonia was reported which was considered as a serious AE. However, this was not related to the study of the drug.

Out of 2010 patients, 44 (2.19%) reported drug-related AEs, out of which 43 patients reported gastrointestinal disorders which included flatulence in 20 patients (most common), abdominal distention in 9, diarrhea in 7 and abdominal pain in 5 patients.

Table 2: Assessment of acarbose continuation

Assessment parameters	*n*=1996	%
Continuation of Acarbose		
Missing	1	0.05
Yes	1938	97.1
No	57	2.9
Reasons for discontinuation of Acarbose*		
Patients with discontinuation	57	2.9
Missing	0	0.00
Patient's decision	21	1.0
Insufficient efficacy	17	0.8
Adverse event	11	0.5

*Multiple responses

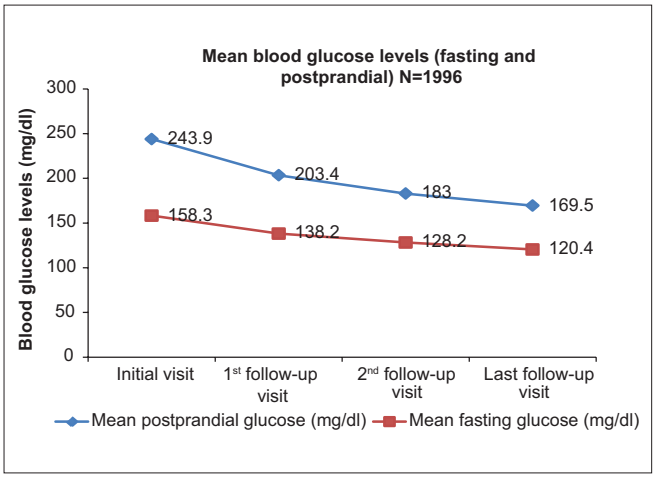

Figure 1: Mean change in 2-h postprandial and fasting blood glucose (mg/dL) at each visit during acarbose treatment

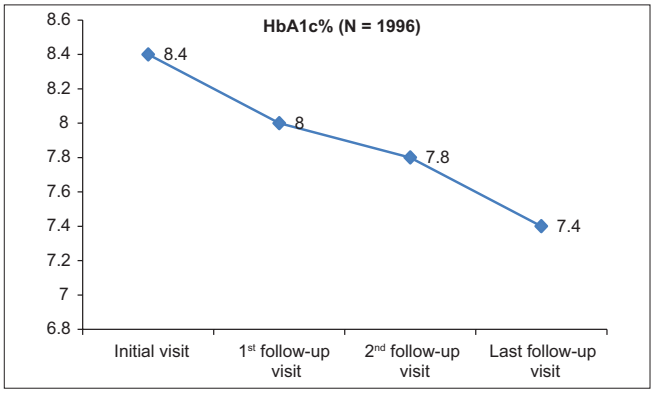

Figure 2: Mean change in HbA1c at each visit during acarbose treatment

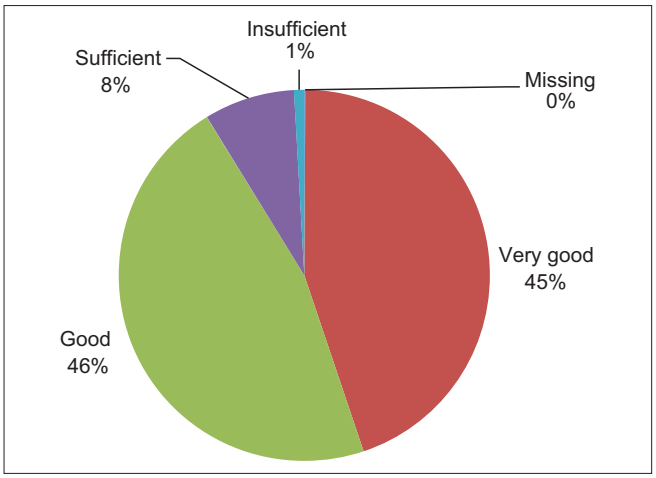

Figure 3: Physician's assessment of efficacy

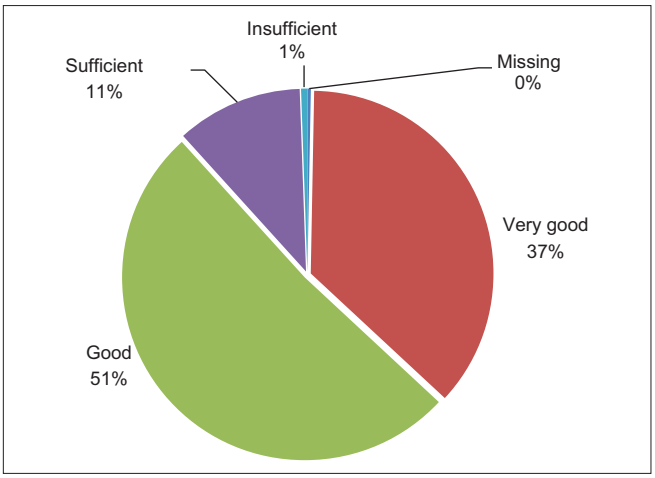

Figure 4: Physician's assessment of tolerability

Table 3: Treatment emergent adverse events

Number of patients with treatment for emergent adverse events	*n*	%
Total patients	2010	100.0
Adverse events	55	2.74
Drug-related AEs	44	2.19
Any gastrointestinal disorders	43	2.14
Flatulence	20	1.00
Abdominal distention	09	0.45
Diarrhea	07	0.35
Abdominal pain	05	0.25
Serious AEs	1	0.05
Serious drug-related AEs	0	0.00
AEs resulting in permanent discontinuation of study drug	13	0.65

AE: Adverse events

Discussion

This is the first study to report data about efficacy of acarbose in large number of T2DM patients across India. The Indian and Chinese population takes more carbohydrate than Caucasians or others leading to greater exposure of carbohydrates on the L-cells, K-cells and I-cells of the intestine as well as the brush border of the intestine which possesses alpha glucosidases. Hence, the drugs working via the glucosidase and incretin pathway have a greater glycemic efficacy in these high glycemic load populations unlike the Western environment, which are lesser carbohydrate predominant, compared to the Indian and Chinese cohort. Also, there is a need of therapeutic agents that target the early stages of T2DM, like the alpha glucosidase enzyme inhibitors such as acarbose, which reduces post-prandial hyperglycemia and hyperinsulinemia and increases GLP-1, may have a more prominent role in diabetes in such settings. In an Indian setting, the role of acarbose is even more significant as our meal component is carbohydrate rich. Acarbose has been shown to improve long-term glycemic control. It is associated with beneficial effects on hyperglycemia, hyperinsulinemia, body weight, and, in some studies, triglyceride levels.[10]

The results demonstrated that acarbose reduced mean 2-h PPG (from 243.9 mg/dl to 169.5 mg/dl), FBG value (158.3 mg/dl to 120.4 mg/dl), and HbA1c (8.4% to 7.4%) from initial visit to last follow-up visit. A study by Jayaram *et al.,* in 2010 evaluated safety and tolerability based on the adverse events reported and assessed efficacy based on changes in fasting, PPG and HbA1c values in India in T2DM. The study concluded that the combination of acarbose and metformin was found to be significantly superior in lowering the FBG ($P < 0.0001$), PPG ($P < 0.0001$) and HbA1c ($P < 0.0001$) at 12 weeks as compared to metformin monotherapy.[17] The present study reported that there was a decrease in body weight (initial 72.7 kg, at last follow-up 71.3 kg) and waist circumference (from 93.5 cm to 91.9 cm) with acarbose treatment during the observation period of 12 weeks. A meta-analysis of 30 acarbose trials reported that the alpha-glucosidase inhibitor (AGI) acarbose decreased HbA1c by 0.8% (95% CI - 0.9 to - 0.7), and was not associated with weight gain in patients with T2DM.[18]

The United Kingdom Prospective Diabetes Study (UKPDS), showed that the blood glucose- and HbA1c-lowering effect of acarbose persisted for at least 3 years, which was not the case with the oral agents, metformin and sulfonylureas, investigated in the same trial.[19] Therefore, acarbose is a reliable anti-diabetic treatment option.

A meta-analysis conducted by Hanefeld *et al.,* 2004[20] reported that acarbose showed favorable trends towards risk reduction for all selected cardiovascular event categories. The risk of "myocardial infarction" was significantly reduced (hazards ratio = 0.36 [95% Cl 0.16-0.80], $P = 0.0120$) as well as risk of "any cardiovascular event" (0.65 [95% Cl 0.48-0.88], $P = 0.0061$). Glycemic control, triglyceride levels, body weight and systolic blood pressure also improved significantly during acarbose treatment. It can be suggested that reduction in PPG with acarbose in this study favors reducing the risk of cardiovascular risk as there is a strong association between PPG and the risk and progression of cardiovascular disease.

In the current study, AEs were reported in 2.74% patients. Drug-related AEs were reported in 2.19% of patients. Other AEs included general disorders and administration site conditions (0.05%), nervous system disorders (0.05%), psychiatric disorders (0.05%), skin and sub-cutaneous tissue disorders (0.10%). Most common gastrointestinal disorder observed was flatulence (43 out of 44 patients). A study conducted by Shihabi *et al.,* 2013, reported that out of 1737 only 107 patients in Middle East and 26 out of 1082 patients in Morocco experienced minor drug-related AEs, which were mainly gastrointestinal. The tolerability of acarbose was rated as very good/good by 80.8% in the Middle East and by 68.6% in Morocco.[21]

The study has the limitations of not being a placebo controlled blinded study. Due to the non-interventional study design, there were no additional diagnostic or monitoring procedures and no allocation of patients to treatment. Also, the study does not report any *P* value, causing difficulty in establishing statistical significance. In T2DM patients, acarbose can be a preferred monotherapy for early stages with high PPG levels to enable patients to benefit from its effect on PPG. In uncontrolled T2DM,

acarbose can be combined with other anti-diabetic agents to counter act their unfavorable effect e.g. on body weight by Sulfonylureas (SUs) while having the advantage of not producing hypoglycemia by themselves. To ensure maximum efficacy, acarbose has to be administered after the first bite of each meal or no later than 15 minutes after the beginning of the meal. Our study had data for continuation of acarbose from all that patients and it was observed that about 97.09% of patients continued acarbose. Acarbose is recognized as a safe drug. The main side-effects are gastrointestinal symptoms, mainly flatulence and diarrhea, and are related to their mechanism of action. These can be minimized by a "start low, go slow" approach. For acarbose, it is suggested to start with 25 mg every day and increase by 25 mg per day once a week till a dose of 50 mg three times a day (TID) with meals is achieved by the 6th week.[22]

However, it can be concluded that acarbose was effective and safe in Indian patients with T2DM. Further, acarbose helps in weight reduction and has very good compliance in patients with T2DM.

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