Brief Communication

Alpha-glucosidase inhibitor, acarbose, improves glycamic control and reduces body weight in type 2 diabetes: Findings on indian patients from the pooled data analysis

Sanjay Kalra, R. K. Sahay[1], O. Schnell[2], W. H. H. Sheu[3], W. Grzeszczak[4], H. Watada[5], S. Soegondo[6], N. Yamamoto[7], J. Weng[8], R. Rathod[9]

Departments of Endocrinology, Bharti Research Institute of Diabetes and Endocrinology Bharti Hospital, Karnal, [1]Osmania Medical College, Hyderabad, India, [8]The Third Affiliated Hospital of Sun Yat-Sen University, Guangzhou, China, [3]Internal Medicine, Taichung Veterans General Hospital, Taichung, Taiwan, [4]Medical University of Silesia, Zabrze, Poland, [6]University of Indonesia, Jakarta, Indonesia, [5]Endocrinology and Metabolism, Juntendo University Graduate School of Medicine, Tokyo, Japan, [2]Forschergruppe Diabetes e.V. at the Helmholtz Center Munich, Munich, Germany, [7]Bayer Healthcare, Global Medical Affairs, Beijing, China, [9]Bayer Healthcare, Bayer Zydus Pharma Private Limited, Thane, India

A B S T R A C T

Alpha-glucosidase inhibitors are widely used especially in Asian countries as a treatment option for type 2 diabetes patients with high postprandial glycemia (PPG). The higher carbohydrate in the Indian 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. This is the subgroup analysis of Indian subjects who participated in the GlucoVIP study that investigated the effectiveness and tolerability of acarbose as add-on or monotherapy in a range of patients with type 2 diabetes mellitus. A total of 1996 Indian patients were included in the effectiveness analysis. After 12.5 weeks (mean), the mean change in 2-hour PPG from baseline was −74.4 mg/dl, mean HbA1c decreased by -1.0%, and mean fasting blood glucose decreased by -37.9 mg/dl. The efficacy of acarbose was rated "very good" or "good" in 91.1% of patients, and tolerability as "very good" or "good" in 88.0% of patients. The results of this observational study suggest that acarbose was effective and well tolerated in the Indian patients with T2DM.

Key words: Acarbose, alpha glucosidase inhibitor, India, postprandial glycemia, type 2 diabetes

INTRODUCTION

Diabetes, with its long-term complications and comorbid conditions associated with it, is a major health hazard. The goal of treatment of diabetes is the prevention of onset and progression of complications. Therapeutic intervention to achieve this goal consists mainly of maintaining good glycemic control.[1] Alpha-glucosidase inhibitors (AGIs) are widely used especially in Asian countries as a treatment option for type 2 diabetes (T2DM) patients with high postprandial glycemia (PPG).[2] Among Asia, the growing burden of T2DM is a serious concern for India due to its growing population and Westernized life style environment.[3] In order to examine the real life effectiveness of an AGI, acarbose, we conducted a prospective observational noninterventional study.[4] The India sub-analysis data was extracted from pooled analysis of 10 large international non-interventional study/post-marketing studies.

AIMS AND OBJECTIVES

This subanalysis of Indian patients from the international, large-scale, observational study (GlucoVIP; diabetes

Corresponding Author: Dr. Sanjay Kalra, Department of Endocrinology, Bharti Research Institute of Diabetes and Endocrinology Bharti Hospital, Karnal, Haryana, India. E-mail: brideknl@gmail.com

treatment by Glucobay® with a special therapeutic View to chosen patient groups [4]) investigated the effectiveness, and tolerability of acarbose as add-on or monotherapy in a range of patients regardless of age, race, sex, or severity of diabetes.

MATERIALS AND METHODS

In this abstract, we report the results of Indian subgroup which was a part of a prospective, noninterventional, noncontrolled, multicenter, multinational, observational study designed to explore the effectiveness of acarbose in a large sample of patients with T2DM under daily-life treatment conditions. Adults with pretreated or untreated T2DM prescribed acarbose as add-on or monotherapy were eligible. Two-hour postprandial blood glucose (2-hour PPG), glycosylated hemoglobin (HbA1c), and fasting blood glucose (FBG) were measured over a 3-month observation period.

RESULTS

Among 15,034 patients valid for the efficacy analysis (mean age was 57.6 years and 92.6% of patients were Asian), 1996 were from India. 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/m². A total of 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 + CHF (16.2%).

Mean (SD) 2-hour PPG decreased from 241.8 (68.3) mg/dl at initial visit to 170.2 (46.5) mg/dl at final visit (after 12.8 [4.1] weeks) in total population, and from 243.9 (64.0) mg/dL at initial visit to 169.5 (40.2) mg/dL at final visit (after 12.5 [2.9] weeks) in an Indian subpopulation [Figure 1].
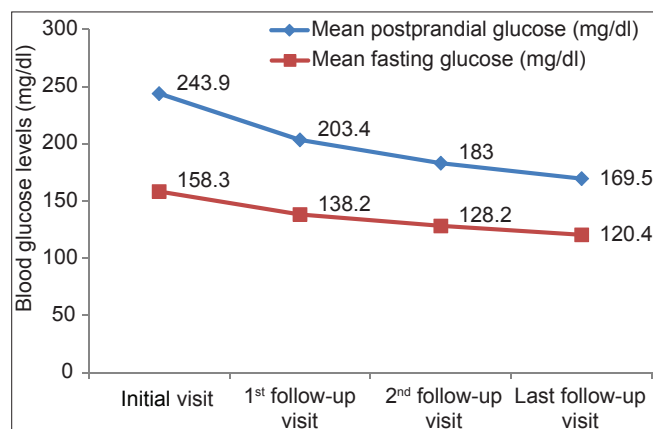
Mean HbA1c decreased from 8.2% (1.6) at initial visit to 7.2% (1.1) in the total population, and from 8.4% (1.3) to 7.4% (0.8) in Indian, mean FBG decreased from 157.4 (49.2) mg/dL to 124.8 (30.5) mg/dL in total population and from 158.3 (45.1) mg/dL to 120.4 (30.1) mg/dL in Indian, and mean body weight (BW) decreased from 70.4 (13.4) kg to 69.5 (12.8) mg/dL in total population and from 72.7 (12.6) kg to 71.3 (12.2) kg in the Indian subgroup.

The efficacy of acarbose was rated 'very good' or 'good' in 85.5% of patients in total population and 91.1% in Indian population, and tolerability as very good' or 'good' in 84.9% of patients in the total population and 88.0% in the Indian population [Figures 2 and 3].

DISCUSSION

This is the first study to report data about efficacy of acarbose in large number of T2DM patients across India. The results demonstrated that acarbose was effective in reducing all glycemic parameters measured, and these improvements were observed by the first follow-up visit, after a mean of only 4.9 weeks. Overall, 2-hour PPG decreased in 94.4% of patients, HbA1c decreased in 52.4% of patients and FBG decreased in 90.6% of patients. These results clearly show that acarbose was extremely effective in reducing PPG over a short time period. The International Diabetes Federation (IDF) 2011 guidelines[5] recommend control of PPG (1-2 hours after a meal) in order to reduce vascular events. Reducing PPG is also important because it significantly contributes to HbA1c in the nearly well-controlled patients.[5,6] Our results indicate that HbA1c was reduced by ≥1% over a 3-month period, which may reflect the significant
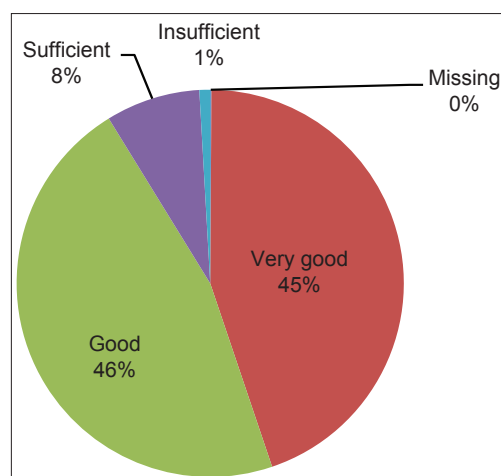

Figure 1: Mean change in blood glucose levels from initial visit to final visit (*N*=1996)

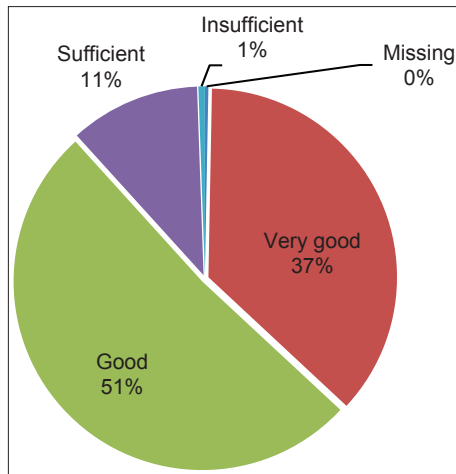**Figure 2:** Physician assessment of efficacy on five-point scale at last visit (*N*=1996)

Figure 3: Physician assessment of tolerability on five-point scale at last visit (*N*=1996)

improvement in PPG. The mean weight reduction of 1.4 kg observed during this study was similar to reductions observed in other large surveillance studies.

The safety data were not analyzed in the current pooled data analysis; however the results from the present study were consistent with the known safety profile of acarbose.[4]

The results of this study show that acarbose is effective and well tolerated in a population of Indian patients with diabetes. Epidemiological studies have shown that complications such as cardiovascular disease, cerebrovascular disease, and diabetic complications are common in populations from India;[7] our study clearly indicates that acarbose is effective in patients from Asian countries with a range of vascular comorbidities.

CONCLUSION

The results of this observational study support the notion that acarbose is effective, safe and, well tolerated in Indian patients with T2DM to the same extent as in the larger international cohort of patients.

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