Brief Communication

Acarbose improves glycemic control and reduces body weight: Subanalysis data of South Asia region

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ABSTRACT

Alpha-glucosidase inhibitors (AGIs) are widely used especially in Asian countries as a treatment option for type 2 diabetes patients with high postprandial glycaemia. However, data from South Asia region is very limited. In order to examine the effect of AGI in real-life setting, 10 PMS/NIS from all over the world from the launch of acarbose to date were pooled in one database and exploratory analysis was performed for glycemic parameters and weight. In total 62,905 patients were pooled from 21 countries and regions. Mean follow up (± SD) was 12.2 ± 4.8 weeks (range 0.1-108.9). From South Asia region (India and Pakistan), 8,738 Asian patients were enrolled. Mean PPG decreased from 240.0 and 261.1 mg/dl at baseline by 70.26 ± 65.10 and 82.96 ± 56.59 mg/dl at the last visit in total and South Asian populations, respectively (n = 53,883; *n* = 7,991, *P* < 0.0001 for both). Mean FPG decreased from 171.6 and 176.5 mg/dl at baseline by 38.48 ± 47.83 and 49.59 ± 41.41 mg/dl at the last visit in total and South Asian populations, respectively (*n* = 56,672; *n* = 7,837, *P* < 0.0001 for both). Mean HbA1c decreased from 8.4 and 8.4% at baseline by 1.11 ± 1.31% and 0.91 ± 0.93% at the last visit in total and South Asian populations, respectively (*n* = 38,843; *n* = 2,343, *P* < 0.0001 for both). Mean relative reduction of body weight (BW) was 1.40 ± 3.28% and 1.10 ± 3.39% at the last visit for mean baseline BW 73.6 and 74.2 kg in total and South Asian populations, respectively (*n* = 54,760; *n* = 7,718, *P* < 0.0001 for both). Consistent with RCT meta-analyses, post-hoc analysis of real-life data showed acarbose treatment improved glycaemic control and reduced the BW. Acarbose treatment in real life setting showed significant reductions in all glycemic parameters and BW in Asian patients from South Asia region.

Key words: Acarbose, diabetes type-2, South Asia

Background and Aims

Alpha-glucosidase inhibitors (AGIs) are widely used especially in Asian countries as a treatment option for type 2 diabetes patients with high postprandial glycaemia.[1] However, data from South Asia region is very limited, therefore, we had conducted 2 international Non-Interventional Studies (NIS)[2] and pooled those with old Post-Marketing Surveillances (PMS).[3-5] Here report subgroup data for Asian patients from South Asia region.

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Methods

In order to examine the effectiveness of AGI in real life setting, we pooled 10 PMS/NISs from all over the world from the launch of acarbose to date, and the data were exploratory analyzed by subgroups. Data from 10 post-marketing surveillance studies (PMS) and non-interventional studies (NIS) were pooled in a single database. These studies included data from 62,905 patients

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from China (27.9%), Germany (18.7%), Pakistan (11.0%), Taiwan (11.0%), Poland (6.8%), Japan (4.4%), Korea (3.9%), India (3.2%), Indonesia (3.1%), and the Philippines (2.7%). Data from 11 other countries are also included as follows: Algeria, Bosnia and Herzegovina, Cambodia, Hong Kong, Malaysia, the Middle East, Morocco, Russia, Singapore, Thailand and Vietnam (all < 2.6%). Data on postprandial plasma glucose (PPG), fasting blood glucose (FBG), glycosylated hemoglobin (HbA1c), and/or BW were collected at the baseline visit and at the post-treatment visits. The final visit ranged from 0.1 to 108.9 weeks, with a mean of 12.2 weeks and a median of 12.9 weeks. A total of 80% of patients had data for the 3-month (±4 weeks) visit, at a mean of 12.4 weeks and a median of 12.9 weeks.

Results

In total 62,905 patients were pooled from 21 countries and regions. Mean follow up (± SD) was 12.2 ± 4.8 weeks (range 0.1-108.9). From South Asia region (India and Pakistan, Tables 1 and 2), 8,738 Asian patients were enrolled.

Mean PPG decreased from 240.0 and 261.1 mg/dl at baseline by 70.26 ± 65.10 and 82.96 ± 56.59 mg/dl at the last visit in total and South Asian populations, respectively (n = 53,883; n = 7,991, P < 0.0001 for both). Mean FPG decreased from 171.6 and 176.5 mg/dl at baseline by 38.48 ± 47.83 and 49.59 ± 41.41 mg/dl at the last visit in total and South Asian populations, respectively (n = 56,672; n = 7,837, P < 0.0001 for both) [Figure 1].

Table 1: Demography – Age, Weight, Height, BMI

		Non-missing	Mean	SD
Male	Age (years)	5003	49.1	10.1
	Weight (kg)	5005	76.0	12.2
	Height (cm)	4883	168.3	9.6
	BMI (kg/m^2)	4826	27.0	4.7
Female	Age (years)	3493	49.1	9.8
	Weight (kg)	3453	71.3	13.3
	Height (cm)	3416	158.9	9.9
	BMI (kg/m^2)	3351	28.4	5.9

Mean HbA1c decreased from 8.4 and 8.4% at baseline by 1.11 ± 1.31% and 0.91 ± 0.93% at the last visit in total and South Asian populations, respectively (n = 38,843; n = 2,343, P < 0.0001 for both) [Figure 1].

Mean relative reduction of body weight (BW) was 1.40 ± 3.28% and 1.10 ± 3.39% at the last visit for mean

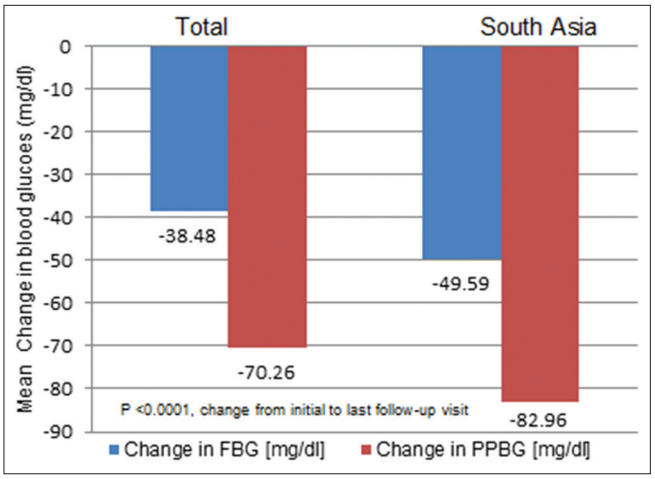

Figure 1: Change in fasting and post-prandial blood glucose levels in total and South Asian population from initial to last follow-up visits (all change statistically significant, P < 0.0001) (Refer text for number of patients)

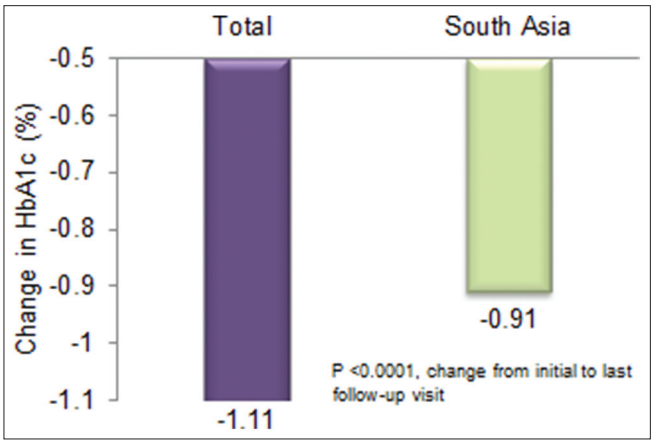

Figure 2: Mean change in HbA1c in total and South Asian population from initial visit to last follow-up visit. (All change, statistically significant, P < 0.0001) (Refer text for number of patients)

Table 2: Demography – BMI classified by Asia/Pacific standard*

BMI group	Total		Missing		Male		Female	
	N	%	*N*	%	*N*	%	*N*	%
Total	8738	100.0	101	100.0	5088	100.0	3549	100.0
Missing	499	5.7	39	38.6	262	5.1	198	5.6
Underweight (<18.5 kg/m^2)	141	1.6	1	1.0	80	1.6	60	1.7
Normal weight (18.5 - <23 kg/m^2)	1234	14.1	7	6.9	759	14.9	468	13.2
At risk of obesity (23 - <25 kg/m^2)	1452	16.6	11	10.9	908	17.8	533	15.0
Obese I (25 - <30 kg/m^2)	3199	36.6	27	26.7	2013	39.6	1159	32.7
Obese II (≥30 kg/m^2)	2213	25.3	16	15.8	1066	21.0	1131	31.9

*For patients from regions South Asia, East Asia, South East Asia and Western Pacific the Asia/Pacific standard was used (Underweight/Normal (<23), Overweight (23-<25), Obese (>=25))

baseline BW 73.6 and 74.2 kg in total and South Asian populations, respectively ($n = 54,760$; $n = 7,718$, $P < 0.0001$ for both) [Figure 2].

Reductions of all glycemic parameters and BW were baseline-dependent (the higher, the more). In the heaviest baseline BW category (≥100 kg), 2.79 ± 4.03% relative reduction in BW ($n = 3,000$, $P < 0.0001$) was observed (total population).

Discussion

The current subanalysis of South Asia data from pooled analysis of 10 NIS/PMS shows consistent improvement in glycemic parameter as reported earlier in published studies.[2-5] Recently, IDF has released the updated guideline and recommended, AGIs as an alternative 1st and 2nd line and as 3rd line agent alone or in combination with other oral antidiabetic agents and/or insulins.[1]

In current pooled analysis, safety data was not analyzed, hence, no further discussion on the topic is possible. However, individually published studies[2-5] confirms that acarbose was very well tolerated and no major safety concerns were reported.

Consistent with RCT meta-analyses,[6] post-hoc analysis of real-life data showed acarbose treatment improved glycaemic control and reduced the BW.

Conclusion

Acarbose treatment in real life setting showed significant reductions in all glycemic parameters and BW in Asian patients from South Asia region.

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