

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Not Applicable
ACTIVE INGREDIENT: Not Applicable

Study No: NIS-CIN-XXX-2011/3
Study Title : A Non-Interventional Study To Evaluate Diabetes Related Quality Of Life, Frequency And Impact Of Hypoglycemia In Type 2 Diabetes Patients On Pharmacotherapy (INSIGHT)

Developmental Phase: Not Applicable
Study Completion Date: 20th February 2013
Date of Report: 23rd January 2014

OBJECTIVES:

Primary objective: To assess the diabetes related quality of life (DQoL) in Type 2 Diabetes Mellitus (T2DM) patients on pharmacotherapy.

Secondary objectives:

1. To assess the frequency and impact of hypoglycemia in relation to HbA1c control with current therapies
2. To assess the disease modifying variables – Body Mass Index (BMI) and blood pressure (BP)

METHODS:

This was a non-interventional, cross-sectional, multicentric study in T2DM patients. 4911 patients diagnosed with T2DM were selected from around 249 primary care clinics/ hospitals across India. Diabetes Pharmacotherapy were distributed in nine different groups (Table 1). Modified Diabetes Quality of Life MDQoL questionnaire used to study the primary objective ie. diabetes related quality of life in T2DM patients on pharmacotherapy was specifically modified to suit diverse Indian population. Impact of hypoglycaemia was determined on Hypoglycemia Fear Scale- Worry (HFS-W) scale and was analysed using ANOVA model with treatment group as fixed effect. The prevalence of diabetic patients with co-morbid conditions and glycemic control was determined by analyzing HbA1c data for sub-groups of obese and non-obese patients and hypertensive and non-hypertensive patients.

Table 1: Study population divided in 9 different treatment groups:

Group	Medications	All subjects (N=4873)
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		n%
Group 1	Metformin	660 (13.5%)
Group 2	Sulfonylurea	231 (4.7%)
Group 3	DPP4i as a single agent	19 (0.4%)
Group 4	Metformin+Sulfonylurea	1606 (33.0%)
Group 5	Metformin with Insulin or Sulfonylurea with Insulin or Metformin+Sulfonylurea with Insulin	484 (9.9%)
Group 6	DPP4i in combination with Sulfonylurea or Insulin	401 (8.2%)
Group 7	DPP4i and metformin	191 (3.9%)
Group 8	GLP-1 agonists with other OHA/insulin	9 (0.2%)
Group 9	Others (Alpha-glucosidase inhibitors +combinations, TZDs and TZD+ combination).	1272 (26.1%)

RESULTS:

Primary Objective: To assess Diabetes related quality of life MDQoL was used to derive at a score value in each of the 9 treatment groups. Total score and mean score were comparable across groups and mean score ranged from 3.9 to 4.1 with group 3 and 6 having the lowest score.

Table 2 Summary of MDQoL Mean Scores in PP Analysis Set

	Group 1 (N=660)	Group 2 (N=231)	Group 3 (N=19)	Group 4 (N=1606)	Group 5 (N=484)	Group 6 (N=401)	Group 7 (N=191)	Group 8 (N=9)	Group 9 (N=1272)
n	657	231	19	1600	484	401	189	9	1262
Mean	4.1	4.1	3.9	4.1	4	3.9	4.1	4	4.1
SD	0.61	0.67	0.71	0.66	0.66	0.67	0.66	0.71	0.69
Minimum	2	2	3	1	2	2	2	3	1
Maximum	5	5	5	5	5	5	5	5	5

Secondary Objective:

1. Impact of hypoglycemia on HFS-W score is found to be highly significant (p-value <.0001). Group 3 shows highest mean score of 0.9 and group 2 shows the lowest score of 0.4.
2. Mean HbA1c value did not vary significantly between the obese and non-obese and hypertensive and non-hypertensive patients. Group 8 alone demonstrated a difference but number of patients in this group is too small to arrive at a conclusive inference.