P0346 – The effectiveness of lixisenatide as an add on therapy to basal insulin in diabetic type 2 patients previously treated with different insulin regimes: real world evidence

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INTRODUCTION

The glucagon-like peptide-1 receptor agonist lixisenatide is effective at reducing glycated hemoglobin (HbA1c) levels in patients with type 2 diabetes mellitus (T2DM). Although lixisenatide as add on therapy to basal insulin has demonstrated equal efficacy as basal bolus insulin therapy in a head-to-head clinical trial, real-world evidence of comparative effectiveness is lacking. This observational study aimed to assess the effectiveness of lixisenatide as add on therapy to basal insulin in diabetic type 2 patients previously treated with different insulin regimes.

METHODS

Data from electronic medical records from several different Clinical Hospital Centers in Croatia were taken retrospectively and analyzed. Patients aged ≥18 years, diagnosed with T2DM, prescribed with lixisenatide and basal insulin were divided in three groups according to the type of previous insulin therapy (premixed insulins 45%, basal bolus insulin therapy 13,5% and basal oral therapy (BOT) 41,4% of the patients). Difference in mean change in HbA1c, body mass index (BMI), total insulin doses, fasting blood glucose (FPG) and prandial blood glucose (PPG) were assessed after 3-6-months of follow-up. The proportion of patients achieving glycemic control (<7.0%) and weight reduction within 3-6 months were determined

RESULTS

The primary outcomes were assessed in 111 patients. Average duration of diabetes was 9,6±5,7 years, average age of participants was 62,9±9,4 years and median insulin treatment duration was 20 months. Lixisenatide added to basal insulin, reduced HbA1c and body weight significantly in all three groups of patients (p<0.001 for all), with the most prominent reduction in the basal bolus group of patients. (p<0.001; 2% reduction vs. 0,6% and 0,8% reduction in premix and BOT group respectively) which had the highest baseline HbA1c compared to premix and BOT treatment groups (9,6±1,8% vs. 8,4±1,2 and 8,5±0.9). Regarding a difference in total insulin dose the reduction was statistically significant in the basal bolus (p = 0.006) and premix group (p <0.001), but not in the basal oral therapy group where a slight increase in the average dose of basal insulin was noted. Dose of basal insulin did not change significantly from baseline to follow up visit. FPG and PPG were also significantly reduced over time in all three groups (p<0.001 for all). A composite outcome (reduction of HbA1c below 7% with any weight loss) was achieved in 27% of total patients included in the study, reduction of HbA1c below 7% was observed in 30% of patients, while 90% of patients experienced weight reduction.

Table 1. Comparison of data obtained at baseline and after 3-6 months of follow up in three groups of patients

Type of insulin regime	Parameters	Baseline Mean±SD	Control visit Mean±SD	p value
premix	weight (kg)	104±14	99±13	p=0.003
	BMI (kg/m^2)	38.1±3.1	36.0±3.1	P=0.039
	total daily basal insulin	40±15	41±12	p<0.001
	Hba1c (%)	8.4±1.2	7.6±0.9	p<0.001
	FBG (mmol/l)	10.1±2.4	7.7±1.8	p<0.001
	PPG (mmol/l)	10.8±2.5	8.7±2	p<0.001
basal	weight (kg)	109±12	104±11	p=0.003
	BMI(kg/m^2)	38.7±3.3	38.6±10	NS
	total daily basal insulin	36±14	37±11	NS
	Hba1c (%)	8.5±0.9	7.6±0.7	p<0.001
	FBG (mmol/l)	8.3±2.4	7.2±1.6	p=0.009
	PPG (mmol/l)	11.4±2.1	8.4±1.7	p<0.001
basal bolus	weight (kg)	107±19	98±14	p<0.001
	BMI (kg/m^2)	36.0±1	33.8±1.1	p=0.039
	total daily basal insulin	51±27	50±24	p=0.006
	Hba1c (%)	9.6±1.8	7.5±0.9	p<0.001
	FBG (mmol/l)	10.3±3	7.6±1.4	p<0.001
	PPG (mmol/l)	12.4±2.9	9.2±2.5	p<0.001

Table 2. Assesment of outcomes according to groups and total number of patients.

Type of insulin regime	Outcome	n	%
Premix	decrease in both BMI and HbA1c < 7%	15	13,5
	decrease in body weight	45	40,9
	decrease in HbA1c < 7	16	14,5
Type of insulin regime	Outcome	n	%
Basal	decrease in both BMI and HbA1c < 7%	10	9
	decrease in body weight	39	35,5
	decrease in HbA1c <7	13	11,8
Type of insulin regime	Outcome	n	%
Basal bolus	decrease in both BMI and HbA1c < 7%	5	4,5
	decrease in body weight	15	13,5
	decrease in HbA1c <7	5	4,5
Total	Outcome	n	%
	decrease in both BMI and HbA1c < 7%	30	27
	decrease in body weight	99	90
	decrease in HbA1c < 7	34	30

CONCLUSION

These results indicate that lixisenatide add on basal insulin treatment (BIT) can improve glycemic control in a population with long-standing type 2 diabetes and previously uncontrolled on other insulin therapy. In addition, dose of basal insulin practically remained unchanged in all groups from the moment of lixisenatide introduction to the therapy which could imply that the lixisenatide is fully responsible for the favorable results at the follow-up visit.