LIXISENATIDE IMPROVES GLYCEMIC CONTROL AND BODY COMPOSITION IN UNCONTROLLED TYPE 2 DIABETIC PATIENTS TREATED WITH INSULIN

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Objective: Evaluate the efficacy and safety of adding Lixisenatide to uncontrolled type 2 diabetic (T2DM) patients treated with insulin.

Methods: A prospective uncontrolled study was designed. Primary endpoints (measured at three and six months) were change in HbA1c, weight and insulin doses. Variables analyzed were: HbA1c level, insulin and other oral hypoglycemic agents (OHA) doses, capillary glucose tests, number and type of hypoglycaemias (glucose < 70 mg/dl), side effects and body composition analysis (Tanita SC-330).

Results: Data from 42 T2DM patients (women: 55%; mean age: 57.7 ± 7.4 years; T2DM duration: 13.5 ± 8.7 years; hypertension: 71%; cardiovascular complications: 26%) treated with insulin and lixixenatide were analyzed. Main results are expressed in tables and graphics.

Table 1. Changes in clinical, metabolic and treatment variables and hypoglycaemia during the study

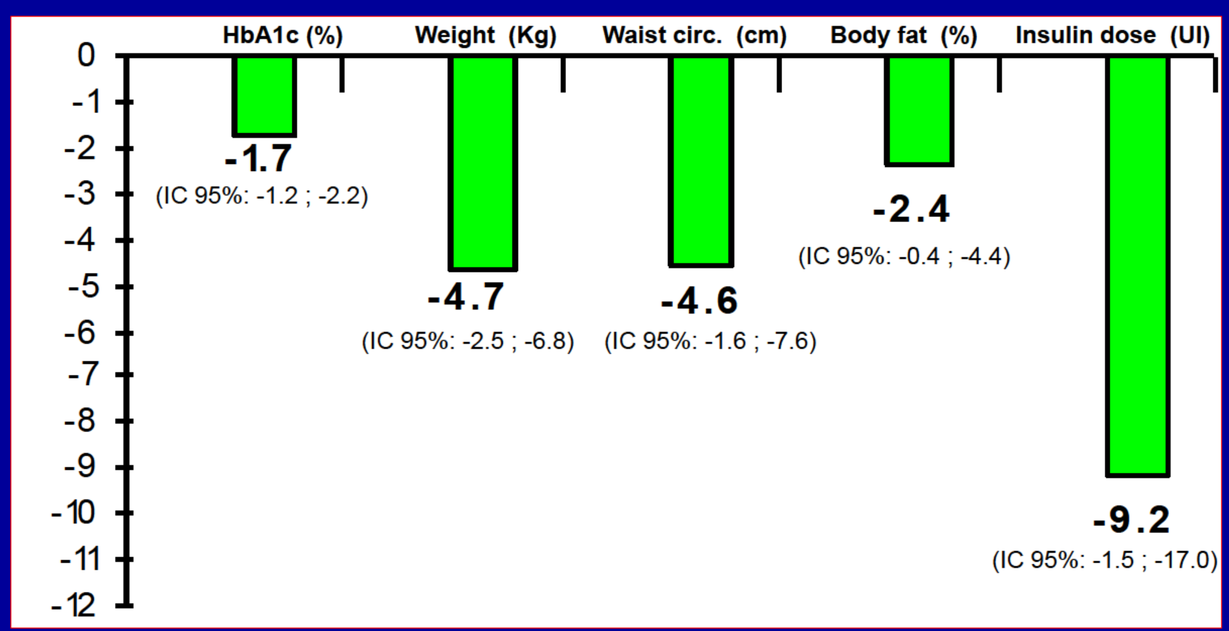
	Basal	3 Months	6 Months	P
Weight (Kg)	99.5 ± 16.5	96.2 ± 14.4	95.2 ± 14.8	<0.001[1]
Waist circumference (cm)	118.0 ± 12.3	115.5 ± 11.6	114.9 ± 14.2	<0.001[1]
Body fat (%)	38.3 ± 8.0	38.5 ± 8.4	34.7 ± 7.9	0.547[2] / 0.015[3]
HbA1c level (%)	9.2 ± 1.7	7.8 ± 1.1	7.6 ± 0.8	<0.001[1]
Insulin injections at day (n)	2.3 ± 1.3	1.8 ± 1.2	1.9 ± 1.3	0.002[2] / 0.047[3]
Patients with rapid insulin (n)	19 (46.3%)	10 (29.4%)	7 (29.2 %)	<0.001[1]
Basal insulin doses (UI)	51.6 ± 24.3	45.3 ± 24.7	40.8 ± 22.2	0.062[2] / 0.048[3]
Rapid insulin doses (UI)	13.9 ± 19.9	9.3 ± 15.5	7.4 ± 13.0	0.002[2] / 0.029[3]
Total insulin doses (UI)	62.7 ± 36.7	53.6 ± 35.6	49.4 ± 30.5	0.055[2] / 0.021[3]
Different type of OHA at day (n)	0.9 ± 0.9	1.2 ± 0.6	1.2 ± 0.6	0.04[2] / 0.119[3]
Capillary glucose test at day (n)	1.8 ± 0.9	1.9 ± 0.9	1.6 ± 0.9	0.99[2] / 0.102[3]
Hypoglycaemia episodes in last month (n)	-	0.6 ± 1.2	1.0 ± 1.7	-

[1] Three and six months vs basal; [2] Three months vs basal; [3] Six months vs basal.

Table 2. Patients leaving the study

Reason for leaving the study	Results
Nausea or vomiting (%)	4 (9.5%)
Hypertransaminasemia	1 (2.4%)
Uncontrolled hyperglycemia	1 (2.4%)
Unknown reason	3 (7.1%)
Total	9 (21.4%)

Graphic 1. Change in main result variables at six months



Conclusions: In our clinical experience, Lixisenatide contributes to improving glycemic control as facilitates weight loss and insulin doses reduction in T2DM patients uncontrolled with insulin.

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