

# EFFICACY AND SAFETY OF SGLT-2 INHIBITOR CANAGLIFLOZIN IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN CLINICAL PRACTICE

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## Introduction

- In clinical trials, the SGLT2 inhibitor Canagliflozin inhibits renal reabsorption of glucose, increases its excretion and reduces hyperglycaemia in patients with type 2 diabetes mellitus (T2DM).
- The increase in glucosuria and diuresis produced, results in a reduction in weight and blood pressure (BP). Moreover, it may cause genital and urinary tract infections.
- However, does Canagliflozin behave in the same way in routine clinical practice?

## Objective

- To make a short-term assessment in routine clinical practice of the efficacy and safety of Canagliflozin in patients with T2DM

## Material and Methods

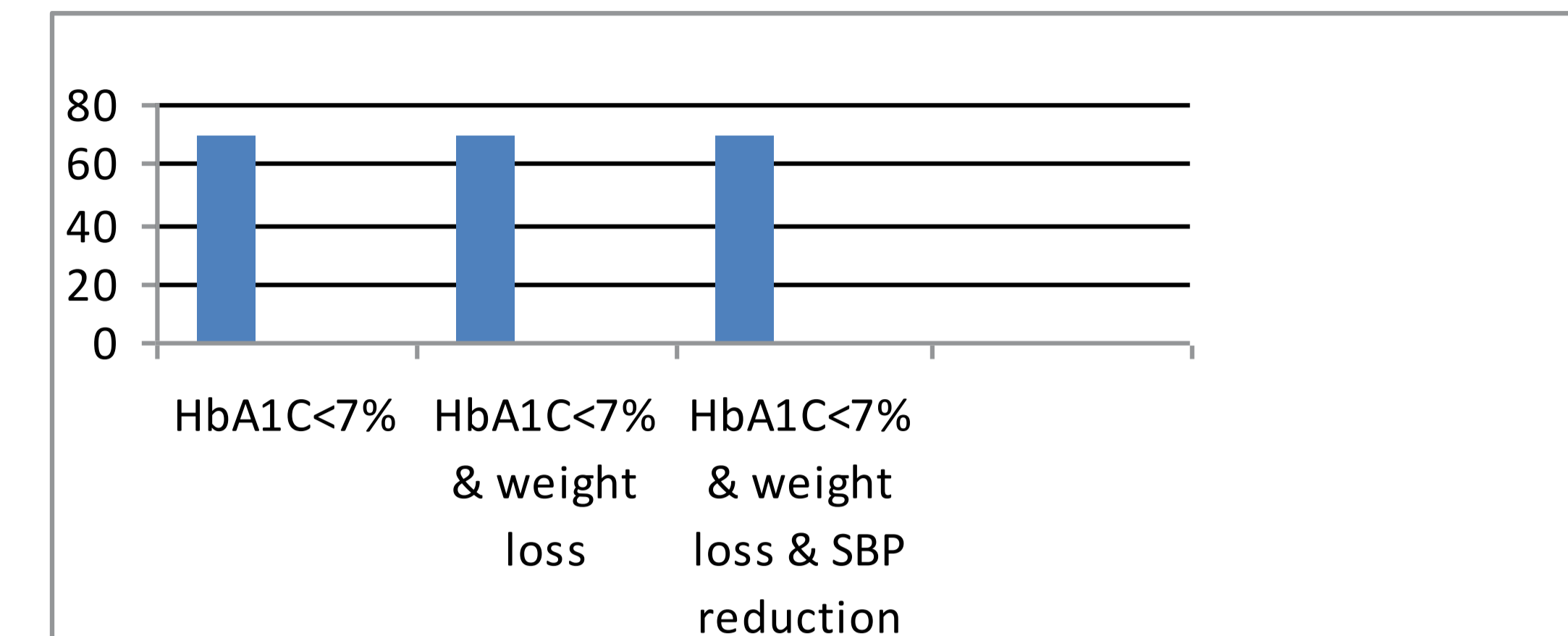
- Thirty-three T2DM patients of 60.4±10.9 years of age and 13.6±7.3 years of evolution (12 women, 21 men), with BMI>30 Kg/m<sup>2</sup>, HbA1C>7% and estimated glomerular filtration rate> 60 ml/min, had Canagliflozin 100 mg/day added to their treatment in monotherapy (n=2), double therapy (n=6), triple therapy (n=7), oral antidiabetic drugs (OADS)+basal Insulin (n=5), OADS+basal bolus (n=10); OADS+rapid insulin (n=1) and basal bolus (n=2).
- They were weighed and HbA1C, fasting glucose (FG), systolic BP (SBP) and diastolic BP (DBP) were measured, before and 3 months after adding Canagliflozin.
- A p<0.05 was considered significant (SPSS, v. 20.0).

## Results

- Baseline characteristics of patients are shown in Table 1
- At 3 months, weight (p<0.001), HbA1c (p=0.000), FG (p=0.000), and SBP (P<0,01) reduction were observed (Table 2).
- The average weight lost was 3.45±2.9 Kg., HbA1c was 1.13±0.83 %, and SBP was 7.7±8.6 mmHg (Table 3).
- 69.2% of patients achieving HbA1c< 7%, and decrease in weight and SBP (Figure 1).
- Only two genital infection and one urinary infection were observed, that evolved well, not requiring treatment discontinuation (Table 3).

**Table 1.** Baseline characteristics of the 33 study subjects with T2DM.

Characteristics	
N	33
Sex (M/F)	21/12
Age (years)	60.4±10.9
Diabetes evolution (years)	13.6±7,3
Weight (Kg.)	86.8±18.2
BMI (Kg/m <sup>2</sup> )	34.2±4.9
Fasting Glucose (mg/dl)	162.1±38.7
HbA1c (%)	8.35±1.48
Systolic Blood pressure (mmHg)	144.3±16.7
Diastolic blood pressure (mmHg)	78.5±9.4
Therapeutic step	
Monotherapy	2
Double therapy	6
Triple therapy	7
OADS + Basal insulin	5
OADS + Basal-bolus	10
OADS + rapid insulin	1
Basal bolus	2
Antidiabetic drugs	
Metformin	30
Sulfonylureas	6
Glinides	1
Pioglitazone	2
DPP4 inhibitors	12
GLP-1 analogs	8
Basal Insulin	17
Rapid Insulin	13



**Figure 1.** Percentage of patients achieving A1c, weight and BP compound goals, 3 months after 100 mg / day of Canagliflozin

**Table 3.** Mean weight loss, mean HbA1c, SBP and DBP reductions; and adverse events, 3 months after 100 mg / day of Canagliflozin in T2DM study patients

OBJECTIVES	
Mean weight loss (Kg.)	-3.45±2.9 (0.0; -5.40)
Mean HbA1c reduction (%)	-1.13±0.83 (0.0; -3.0)
Mean SBP reduction (mmHg)	-7.7±8.6 (6; -25)
Mean DBP reduction (mmHg)	-3.5±6.9 (5; -16)
Urinary infections	1/33 (3%)
Genital infections	2/33 (6,1%)

**Table 2.** Weight, HbA1c and blood pressure before and after 3 months of taking a dose of 100 mg / day of canagliflozin in T2DM study patients.

	Before Canagliflozin (N=33)	After Canagliflozin (3 months) (N=33)	p
Weight (Kg.)	86.8±18.2	83.4±18.6	<0.001
HbA1c (%)	8.35±1.48	7.22±1.09	0.000
Systolic blood pressure (mmHg)	144.3±16.7	136.6±20.1	<0.01
Diastolic blood pressure (mmHg)	78.5±9.4	75.0±12.3	0.106

## Conclusion

- In clinical practice and in the short-term, Canagliflozin added to the treatment of poorly controlled and obese T2DM patients, at any therapeutic level, was translated into a reduction in weight, HbA1c and SBP in more than 2/3 parts, with few adverse effects.
- Long-term studies with more number of patients should be conducted to find out whether the results are maintained..

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