# EARLY 'REAL WORLD' DATA ON DAPAGLIFLOZIN:

## effective glucose control, blood pressure reduction, weight loss, and reduced medication burden


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## Introduction

**Dapagliflozin is the first medication in the new class of sodium-glucose cotransporter 2 (SGLT2) inhibitors licensed in the UK. Improved glycaemic control and weight loss have been demonstrated in pre-registration clinical trials [1-4] but effectiveness in clinical practice has not yet been reported. We aimed to measure clinical effectiveness of dapagliflozin in real world patients.**

## Methods

We performed **a retrospective systematic case-note audit** of all patients started on dapagliflozin in the diabetes outpatient specialist clinic of a London hospital.

### Study aims:

1. Measure changes in glucose control, blood pressure and weight loss in people treated with dapagliflozin.
2. Measure changes in concurrent medication use.
3. Identify baseline predictors of response to dapagliflozin.

## Results

96 people with type 2 diabetes were included in the final analysis .

### Glycaemic control

The mean change in HbA1c was -0.84% (-9.2 mmol/mol). 42% had an HbA1c reduction ≥ 1%; 29% had no reduction.

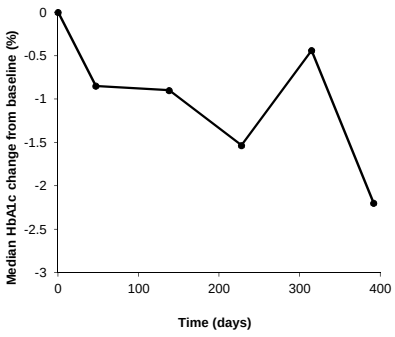


**Figure 1. Median HbA1c change since initiation of dapagliflozin.**

### Weight

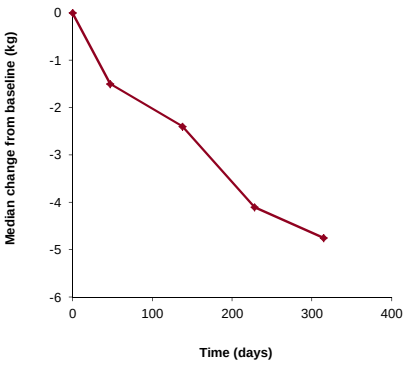


**Figure 2. Median weight change since initiation of dapagliflozin.**

### Blood pressure

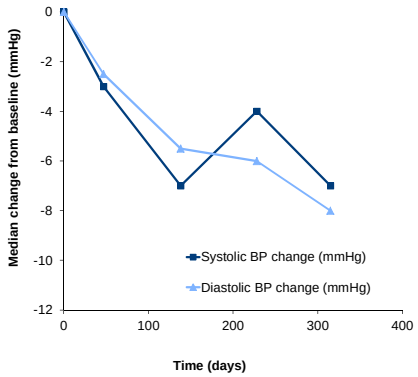


**Figure 3. Median changes in blood pressure since initiation of dapagliflozin**

### Comparison with clinical trials

Efficacy was similar to that reported in trials of similar duration . Side effect rates were also similar but the rate of discontinuation due to side effects (22%) was higher than in trials (3-4%) [1-2].

### Concurrent medication use

36 (38%) of people tolerating dapagliflozin were able to stop or reduce one or more other diabetes medication. 18 (26%) people had medication doses increased or an additional medication added.

### Adverse effects

Adverse effects were recorded for 36 (38%) people. Genital candidiasis, nocturia, and polyuria were the most common adverse effects.

### Predictors of response

Poor glycaemic control was the only predictor of improvement in HbA1c and higher BMI at baseline the only identified predictor of greater weight reduction.

## Summary

**Dapagliflozin is as effective in real world clinical practice as suggested by pre-registration trial data. It has additional benefits beyond glycaemic control; reduction of blood pressure, weight loss, and reduced need for concomitant diabetes medications. However dapagliflozin is not as well tolerated in real world patients as in participants of clinical trials.**

## References


1. Ferrannini E, Ramos SJ, Salsali A, Tang W, List JF: **Dapagliflozin monotherapy in type 2 diabetic patients with inadequate glycemic control by diet and exercise: a randomized, double-blind, placebo-controlled, phase 3 trial.** *Diabetes Care* 2010, **33:**2217-2224.
2. Bailey CJ, Gross JL, Pieters A, Bastien A, List JF: **Effect of dapagliflozin in patients with type 2 diabetes who have inadequate glycaemic control with metformin: a randomised, double-blind, placebo-controlled trial.** *Lancet* 2010, **375:**2223-2233.
3. Strojek K, Yoon KH, Hruba V, Elze M, Langkilde AM, Parikh S: **Effect of dapagliflozin in patients with type 2 diabetes who have inadequate glycaemic control with glimepiride: a randomized, 24-week, double-blind, placebo-controlled trial.** *Diabetes Obes Metab* 2011, **13:**928-938.
4. Wilding JP, Norwood P, T'Joen C, Bastien A, List JF, Fiedorek FT: **A study of dapagliflozin in patients with type 2 diabetes receiving high doses of insulin plus insulin sensitizers: applicability of a novel insulin-independent treatment.** *Diabetes Care* 2009, **32:**1656-1662.


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