

# DTB CME/CPD Answers



Drug and Therapeutics Bulletin

## ▼ Empagliflozin, diabetes and outcomes

### Question 1

Empagliflozin is the third sodium-glucose co-transporter-2 (SGLT2) inhibitor licensed for use in the UK for adults with type 2 diabetes to improve glycaemic control. Which one of the following statements regarding empagliflozin is correct?

- Empagliflozin should be initiated at 25mg daily in patients requiring tight glycaemic control
- Empagliflozin inhibits CYP3A4 activity
- Empagliflozin should be discontinued if eGFR persistently falls below 60mL/min/1.73m<sup>2</sup>
- Diabetic ketoacidosis (DKA) has been reported with empagliflozin**
- Empagliflozin should be initiated with caution in patients aged ≥85 years due to risk of volume depletion

**Answer: d.** Recent safety alerts from the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) have highlighted that rare but serious and sometimes fatal cases of DKA have been reported with SGLT2 inhibitors.

### Question 2

The primary endpoint of four phase III double-blind placebo-controlled trials of empagliflozin was the change from baseline HbA<sub>1c</sub><sup>i</sup> at 24 weeks. Compared with placebo, what was the range of HbA<sub>1c</sub> reductions associated with empagliflozin 10mg in the phase III studies?

- 0.79% to -0.85%
- 0.48% to -0.74%**
- 0.38% to -0.65%
- 0.29% to -0.54%
- 0.19% to -0.37%

**Answer: b.** At 24 weeks, empagliflozin produced statistically significant reductions in HbA<sub>1c</sub> compared with placebo (primary outcome). Across the studies, the difference from placebo in the absolute reduction of HbA<sub>1c</sub> from baseline ranged from -0.48% to -0.74% for empagliflozin 10mg.

<sup>i</sup> The HbA<sub>1c</sub> units are reported from the original studies. To convert from the DCCT unit (%) to the IFCC unit (mmol/mol) please see *DTB* 2010; 48:23-4.<sup>6</sup>

### Question 3

The effect of empagliflozin on cardiovascular outcomes in patients with type 2 diabetes and a history of cardiovascular disease was investigated in the EMPA-REG OUTCOME non-inferiority double-blind placebo-controlled trial. What was the number-needed-to-treat (NNT) to prevent the primary outcome (a composite of death from cardiovascular causes, non-fatal myocardial infarction or non-fatal stroke)?

- 107
- 93
- 63**
- 27
- 17

**Answer: c.** The primary outcome occurred in 10.5% of patients in the empagliflozin group compared with 12.1% in the placebo group (HR 0.86, 95.02% CI 0.74 to 0.99, p<0.001 for non-inferiority; p=0.04 for superiority). The reduction in the primary composite outcome corresponds to a NNT of 63 patients for 2.6 years to prevent one event.

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### Question 4

In pooled data from the pivotal trials of empagliflozin, what percentage of patients receiving empagliflozin 25mg had genital infections?

- a. 0.9%
- b. 1.5%
- c. 2.7%
- d. 4.7%
- e. 11.5%

Answer: d. Pooled data from the pivotal trials showed similar rates of adverse effects with empagliflozin 10mg, 25mg and placebo (71.8%, 70.1% and 74.1% respectively). There was an increased risk of genital infections (e.g. vulvovaginitis, balanitis) with empagliflozin 10mg and 25mg (4.4% and 4.7%) compared with placebo (1.1%); more common in women than in men.

### Question 5

According to National Institute for Health and Care Excellence (NICE) recommendations for treating type 2 diabetes, empagliflozin is an option as part of triple therapy with metformin and which one of the following drugs?

- a. sitagliptin
- b. pioglitazone
- c. exenatide
- d. vildagliptin
- e. liraglutide

Answer: b. NICE recommends empagliflozin as an option for type 2 diabetes as part of triple therapy with metformin and a sulfonylurea or metformin and a thiazolidinedione (pioglitazone).