Characteristics and treatment outcomes of patients treated with empagliflozin in the Association of British Clinical Diabetologists (ABCD) Nationwide Empagliflozin Audit

Ken Y Thong[1], Jonathan Chung-Wah-Cheong[1], Mahender Yadagiri[2], Melissa L Cull[2], Alex Bickerton[3], Suzanne M Phillips[4], Alison Evans[4], Devesh K Sennik[5], Anurita Rohilla[5], Hazel Reid[6], Davis S Morris[7], Marc Atkin[8], Anthony M Robinsonl[8], David M Williams[8], Jeffrey W Stephens[9], Karen Adamson[6], Ian W Gallen[10], Robert E Ryder[2]

[1]*Perth, Australia*, [2]*Birmingham*, *United Kingdom*, [3]*Yeovil*, *United Kingdom*, [4]*Gloucester*, *United Kingdom*,

[5]*Essex*, *United Kingdom,* [6]*Livingston*, *United Kingdom*, [7]*Shrewsbury*, *United Kingdom,* [8]*Bath, United Kingdom,* [9]*Swansea, United Kingdom,* [10]*Reading, United Kingdom*

INTRODUCTION

- Empagliflozin, an inhibitor of sodium-glucose cotransporter 2, improves glycaemia, weight and blood pressure in patients with type 2 diabetes.
- The use of empagliflozin in clinical practice ("real world") as compared with clinical trials may provide different results.
- We investigated characteristics and outcomes of patients treated with empagliflozin in a large scale audit of routine clinical practice in the UK.

METHODS

The ABCD Nationwide Empagliflozin Audit

- The Association of British Clinical Diabetologists (ABCD) conducted a large scale audit of the use of empagliflozin routinely initiated clinical practice in the UK.
- Participating diabetes centres provided anonymised information of patient initiated on empagliflozin including patient demographics, baseline metabolic control and diabetes treatment, and outcomes and adverse events after starting empagliflozin.
- Data was collected between December 2014 to September 2018.

Outcomes

- We analysed baseline characteristics of patients initiating empagliflozin. Results were compared with a pooled analysis of 15 phase I-III clinical trials of empagliflozin (1) and the EMPA-REG study (2).
- Treatment efficacy was compared with pooled data from phase III clinical trials (3).

Subjects

- Data on 2081 patients with diabetes with at least one follow-up visit after empagliflozin initiation was received.
- 134 patients were excluded (type 1 diabetes = 13, switched from dapagliflozin = 3, baseline HbA1c < 7.0% = 118).
- Remaining 1947 patients were analysed

RESULTS

Table 1: Baseline characteristics of patients initiated on empagliflozin in clinical practice in the ABCD audit as compared with clinical trials.

	ABCD audit	Phase I-III trials (pooled) Empagliflozin 10mg*	EMPA-REG Empagliflozin 10 and 25mg pooled
Age (years)	59.9 ± 9.9	60.7 ± 9.5	63.1 ± 8.6
Gender (%Male)	62.1%	64.7%	71.2%
Duration of diagnosis > 5 years	51.6%	73.3%	82.1%
HbA1c (%)	9.41 ± 1.43	8.05 ± 0.84	8.07 ±0.85
Weight (kg)	99.6 ± 20.8	85.3 ± 19.5	86.2 ± 18.9
BMI (kg/m^2)	33.6 ± 9.1	30.4 ±5.5	30.6 ± 5.3
eGFR (ml/min/1.73 m^2)			
>90	44.9%	28.5%	22.4%
60-89	49.9%	54.1%	51.7%
45-59	5.1%	17.1%	25.9%
30-44	0.1%		

*Results for phase I-III clinical trials were similar for empagliflozin dose 10mg vs 25mg. Data for 10mg is presented above.

Table 2: Treatment response to empagliflozin in the ABCD audit as compared with clinical trials

	ABCD audit	Phase III Clinical trials (Empagliflozin 10 and 25mg)
Baseline HbA1c (%)	9.41 ± 1.43	Range 7.18 to 8.30
HbA1c change (%)	-1.35 ± 1.49	Range -0.59 to -0.82
Baseline weight (kg)	99.6 ± 20.8	Range 77.1 to 94.7
Weight change (kg)	-3.6 ± 5.1	Range -1.6 to -3.2
Baseline SBP (mmHg)	134 ± 18	126 to 134
SBP change	-5 ± 14	Range -3 to -5

- The proportion of patients on empagliflozin 25mg vs 10mg in the first follow up visit in the ABCD audit was 63.7% vs 36.3%.
- The proportion of patients in the ABCD audit who were on GLP-1 receptor agonist or insulin at baseline were 13.7% and 20.1%, respectively. In EMPA-REG, these were 2.7% and 48.0%, respectively.

CONCLUSION

- An audit of empagliflozin use in the UK revealed poorly controlled diabetes being frequently encountered in clinical practice.
- Similar with clinical trials, the audit involved more men then women.
- Co-prescriptions of empagliflozin with GLP-1 receptor agonists and insulin were common.
- The audit showed excellent adherence to prescribing guidelines in relation to avoiding empagliflozin use in patients with eGFR<45 ml/min/1.73m^2.
- Efficacy of treatment with empagliflozin in clinical practice was similar to clinical trials, taking into account the poorer metabolic control among patients in the ABCD audit.

REFERENCE

1. Kohler S et al. Safety and tolerability of empagliflozin in patients with type 2 diabetes: pooled analysis of phase I-III clinical trials. Adv Ther 2017; 34: 1707-1726
2. Zinman B et al. Empagliflozin, cardiovascular outcomes and Mortality in type 2 diabetes. N Engl J Med 2015; 373: 2117-2128 (Supplementary Appendix)
3. Levine MJ. Empagliflozin for type 2 diabetes mellitus: an overview of phase 3 clinical trials. Current Diabetes Reviews 2017; 13: 405-423

ACKNOWLEDGEMENT

We thank all the nationwide contributors for submitting data of patients on empagliflozin.