Knowsley Clinical Commissioning Group

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An audit of sodium-glucose cotransporter 2 inhibitor (SGLT2i) use in a specialist community service: are the NICE Technology Appraisal (TA) guidelines too restrictive?

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BACKGROUND

Knowsley is situated in the North West of England, close to Liverpool with a population of approximately 160 000 people. Levels of deprivation are relatively high. The prevalence of diabetes in Knowsley is 6.9% (2013/14).

In 2013, 2014 and 2015 respectively the National Institute for health and care Excellence (NICE) published Technological Appraisal Guidance (TA guidance) for the use of dapagliflozin, canagliflozin and empaglifozin.

AIMS

1. To assess if prescribing of the new SGLT2i drugs by the specialist diabetes community service complies with current TA guidance.
2. To examine the effect of SGLT2i drugs on BP, HbA1c, renal profile, cholesterol and weight.

METHODS

The sample included all patients started on an SGLT2i drug at the Knowsley Community Diabetes Service clinics between 1 April 2015 and 30 September 2015 inclusive.

- Hospital and primary care patient records were examined for:
  - Drugs taken concurrently with SGLT2i drugs
  - Blood results
  - Patient demographics
- In cases where online patient records were incomplete ,written notes filed locally were inspected for the same information.
- Results were collected at baseline before treatment and at last available clinic appointment (cut off date 15/01/16).

COHORT

Total of 37 patients

- 2 excluded as no longer on SGLT2i treatment.
- 3 excluded as GP commenced treatment.

- Average age 55 (range 28-75)
- Dapagliflozin 21
- Canagliflozin 11
- Empagliflozin 0
- M:F = 18:14

Average length of treatment before last clinic appointment = 24 weeks (range 8-57 weeks)

RESULTS

In total **17** (53%) prescribed within TA guidelines and **15** (47%) prescribed outside guidance. Unpaired t-tests were used to calculate significance values.

Prescribed within guidance

Variable	Pre Rx mean	Post Rx mean	P
HbA1c (mmol/mol)	77.3	67.6	0.0721
Weight (kg)	112.7	105.5	0.2692
BMI	37.1	35.5	0.2085
SBP (mmHg)	143	140	0.6028
DBP (mmHg)	80	79	0.8363

Prescribed outside guidance

Variable	Pre Rx mean	Post Rx mean	P
HbA1c (mmol/mol)	**82.1**	**65.4**	**0.0294**
Weight (Kg)	98.5	95.3	0.6174
BMI	35.4	34.2	0.6023
SBP (mmHg)	143	134	0.2952
DBP (mmHg)	82	80	0.5384

Reasons for prescribing outside guidelines:

- Reluctant to start insulin = 9
- Unsuitable for GLP-1 (secondary to pancreatitis) = 1
- To help with weight loss = 2
- No reason documented = 3

<u>Concurrent drug treatment outside NICE guidance:</u>

Dapagliflozin: The most common co-prescription was with dipeptidyl peptidase-4 inhibitor (DPP-4i) (6 patients), and others were with a GLP-1 receptor agonist or sulphonylurea.

Canagliflozin: Prescribed alongside DPP4-i (3 patients), and as an additional agent to triple oral therapy regimes. 1 patient was co-prescribed with gliclazide, metformin, insulin and a GLP-1 receptor agonist.

There was no significant difference in HbA1c reduction between dapagliflozin and canaglifozin outside of guidance (p=0.2876), or between these treatments for patients prescribed within guidance (p= 0.3961).

There was no significant difference in HbA1c reduction between those prescribed SGLT2i drugs alongside a DPP-4i and those prescribed without a DPP-4i (p=0.4163).

DISCUSSION

Glycated Hb reduction in patients prescribed outside guidance was greater than in patients prescribed within guidance (17 mmol/mol vs 9 mmol/mol). Reductions in weight, systolic BP and diastolic BP were seen in both groups.

However, there were different average lengths of treatment at last available appointment between the two groups. Those within guidance averaged 21.9 weeks of follow-up compared to those outside guidance treatment (24.1weeks).

The Knowsley community diabetes clinic is a multidisciplinary clinic in which patients are seen by specialist medical , nursing and dietetic staff. Lifestyle changes are actively encouraged and all medication is actively titrated on a regular basis. Therefore, the improvements seen in HbA1c, weight and blood pressure will be due to a combination of interventions.

CONCLUSION

- The addition of SGLT2 inhibitor drugs as a class can lead to reductions in HbA1c, weight, BMI and blood pressure.
- There were no significant differences between the two main SGLT2 inhibitor drugs (dapagliflozin and canagliflozin) in this audit.
- There was a greater reduction in HbA1c in the group prescribed outside NICE TA guidance as compared with the group prescribed within NICE TA guidance.
- This suggests that use of SGLT2i drugs within license but outside of NICE TA guidance can be effective .

REFERENCES: NICE Technology Appraisal 288, 315, and 336.