Does dapagliflozin affect the metabolic response in patients with elevated alanine aminotransferase (ALT) and Type 2 diabetes?: the Association of British Clinical Diabetologists (ABCD) nationwide dapagliflozin audit

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Aims

To evaluate the effect of: (1) dapagliflozin on metabolic response in patients with elevated alanine aminotransferase (ALT); (2) baseline ALT on metabolic response to dapagliflozin

Collected anonymised data of patients treated with dapagliflozin in the UK
- Patient demographics
- HbA1c, weight, ALT
- Diabetes medications
- Adverse events

Dates of Audit 2014-15
Centres 44
Contributors 129
Total Patients 943

Methods

- Selection of patients with both baseline and follow up ALT values with a median of 26±8.2 weeks
- Categorised into three groups depending on baseline ALT- ALT<30U/l, ALT30-50U/l and ALT>50U/l
- Descriptive analysis
- Changes in ALT, weight and HbA1c over time were calculated within and between ALT groups (Wilcoxon signed rank test)
- The relationship between baseline variables including ALT and the metabolic response was assessed (Spearman's correlation).

Results

Baseline Characteristics

<table>
<thead>
<tr>
<th>ALT&lt;30U/l</th>
<th>ALT 30-50U/l</th>
<th>ALT&gt;50U/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=145 (49.8)</td>
<td>n=79 (27.1)</td>
<td>n=43 (14.7)</td>
</tr>
</tbody>
</table>

Males(%) 73.3
Age(years) 56.1±8.5
Diabetes duration(yrs) 11.0(6.2-16.0)
HbA1c(mm/mol) 80.3±17.4
HbA1c(%) 9.5±1.6
BMI(kg/m²) 35.1±9.6
Weight(Kg) 98.0±21.1
ALT(U/l) 21.0(16.2-24.1)

Correlation

<table>
<thead>
<tr>
<th>Change in ALT</th>
<th>Correlation coefficient</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>-0.05</td>
<td>0.39</td>
<td></td>
</tr>
<tr>
<td>0.20</td>
<td>&lt;0.001</td>
<td></td>
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<tr>
<td>0.70</td>
<td>&lt;0.001</td>
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Conclusions

-Apart from positive impact on glycaemic control and weight, dapagliflozin has a statistically and clinically significant response on ALT reduction in Type 2 diabetes patients with a high baseline ALT≥30U/l.

-This result may have may have implications regarding non-alcoholic fatty liver disease, which is associated with Type 2 diabetes.

Acknowledgment

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