

Title: Association of British Clinical Diabetologists (ABCD) nationwide exenatide audit

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Presentation Number: 741

Background and aims: In December 2008, 18 months after the launch of exenatide in the UK, ABCD launched a 9 month project to accelerate understanding of the new agent, through a nationwide audit of its use in real clinical practise.

Materials and methods: A password protected on-line questionnaire for collection of anonymised patient data. Diabetes specialists in the UK were given persistent email encouragement to submit their data.

Results: There has been a dramatic response such that already we have data promised on 7559, data submitted on 5313 and data available for analysis on 3913 patients (mean (+/- SD) age 54.6 (+/- 10.4) years, 2167/3913 (55.4%) male), with all these numbers rising relentlessly. First analysis of the data thus far showed that in response to exenatide mean (+/- SD) HbA1c, weight and body mass index fell as follows: HbA1c by 0.75 from 9.42 (+/- 1.19) to 8.65 (+/- 1.22)% ($p < 10^{-126}$), weight by 4.9 from 114 (+/- 23.3) to 109.1 (+/- 22.6) kg ($p < 10^{-15}$), BMI by 1.74 from 39.89 (+/- 7.5) to 38.15 (+/- 7.24) kg/m² ($p < 10^{-16}$). The weight reduction was variable with some patients showing dramatic response (see figure). A similar wide variability in HbA1c response was observed. Factors accounting for variability in weight response included: patients with osmotic symptoms who increased weight as exenatide controlled glycaemia; patients in whom discontinuation or reduction of insulin, glitazones and/or sulphonylureas contributed to weight loss. Factors accounting for variability in HbA1c response included: patients in whom discontinuation or reduction of other antidiabetic drugs led to worsening glycaemic control; patients with dramatic weight loss and concurrent dramatic reduction in HbA1c. Other reported benefits included return of ovulation in polycystic ovary syndrome and improvement in obstructive sleep apnoea. Gastrointestinal side effects were reported in 1122/3913 (28.7%) (transient in 773/3913 (19.7%), stopped exenatide temporarily in 67/3913 (1.7%), stopped exenatide permanently in 282/3913 (7.2%)). 1763/3913 (45%) patients were on insulin prior to exenatide. Hypoglycaemia rate increased from 104/3913 (2.7%) prior to 177/3913 (4.5%) after exenatide. 7/3913 (0.18%) cases of pancreatitis were reported.

Conclusion: The ABCD nationwide exenatide audit has already generated a very substantial clinical database which is expanding rapidly. First analysis has revealed responders and non responders and that the responses are very varied but sometimes dramatic. The 9 month project is scheduled to finish by September 2009. Further detailed analysis of the expanding database will be undertaken to define the factors associated with different degrees of response, and the extent to which factors such as change in medication, initial weight, BMI and HbA1c, and duration of diabetes contribute to response. Detailed analysis of the response against time and cases of pancreatitis will also be performed.

