Findings from the Association of British Clinical Diabetologists (ABCD) nationwide exenatide and liraglutide audits

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Key points

- The GLP-1 receptor agonists, exenatide and liraglutide, were launched in the UK in 2007 and 2009, respectively, for the treatment of type 2 diabetes. ABCD undertook nationwide audits of their use in real clinical practice in order to determine their effectiveness in reducing HbA_{1c} and weight, their effects on blood pressure and lipids, and their adverse effects
- Patients appeared to achieve greater HbA_{1c} reduction but lesser weight reduction in the liraglutide audit compared with the exenatide audit. However, a major factor contributing to this was lesser insulin and thiazolidinedione discontinuation in the liraglutide audit, reflecting the fact that the exenatide audit was conducted before the liraglutide audit and that during the exenatide audit clinicians learned that such reductions were often not necessary
- There was associated lowering of systolic blood pressure, total cholesterol and triglycerides with exenatide and liraglutide. Lower diastolic blood pressure was associated with liraglutide
- In both audits, stopping insulin was associated with greater weight reduction but lesser impact on HbA_{1c} than continuing with insulin. The combination of insulin plus exenatide was on average less effective and less well tolerated; however, a considerable proportion of patients obtained significant benefit. Hence, it is important not to stop insulin when starting exenatide – clinicians should aim to wean patients off insulin when this is appropriate

Introduction

Exenatide (Byetta®, Amylin Pharmaceuticals, Inc.) was approved by the European Medicines Agency in 2006 for the treatment of type 2 diabetes in patients on metformin and/or sulphonylureas with inadequate response on maximally tolerated doses of these agents.[1] It represented the first of a new class of drugs that lowers blood glucose by mimicking the glucagon-like peptide-1 (GLP-1) hormone in the gut. Major advantages of exenatide include being able to promote weight loss, having a low risk of causing hypoglycaemia (and thus less requirement for glucose monitoring) and the convenience of a fixed-dose preparation. However, its use can be limited by troublesome gastrointestinal (GI) side effects.[2,3]

The Association of British Clinical Diabetologists (ABCD) website incorporates Microsoft Sharepoint technology, which facilitates the shared collection of data in a password-protected area. Following the launch of exenatide in the UK in May 2007, many diabetologists who used it found it effective in reducing both HbA_{1c} and weight. In response to this, ABCD set up a Sharepoint questionnaire on its website to collect anonymised data on patients using exenatide in the UK between 2007 and 2009. ABCD members were encouraged by email to submit the data and clinicians who were not ABCD members were also invited to join in. A total of 315 contributors from 126 centres contributed data on 6717 patients.[4]

In July 2009, another GLP-1 receptor agonist, liraglutide (Victoza®, Novo Nordisk) was launched in the UK. In the wake of the success of the exenatide audit a similar audit with an improved data collection tool was established for a nationwide liraglutide audit, which is ongoing at the time of writing. The data in this presentation concerns those collected up to February 2011. This deadline was set deliberately to enable presentation of preliminary data at the Diabetes UK Annual Professional Conference in April 2011. By that time, 210 contributors from 264 centres had entered data on 3010 patients in the liraglutide audit. Figure 1 shows the centres contributing to the audits; the size of the circles represents the number of patients contributed by that centre. Table 1 shows the baseline characteristics of the patients in each of the audits. For the purposes of data comparison in the exenatide and liraglutide audits only the data on the 2303 patients who had not switched from exenatide to liraglutide were considered.[4]

Figure 1: Nationwide contribution to the ABCD exenatide and liraglutide national audit – the number of patients submitted by each centre is proportional to the size of the circle.

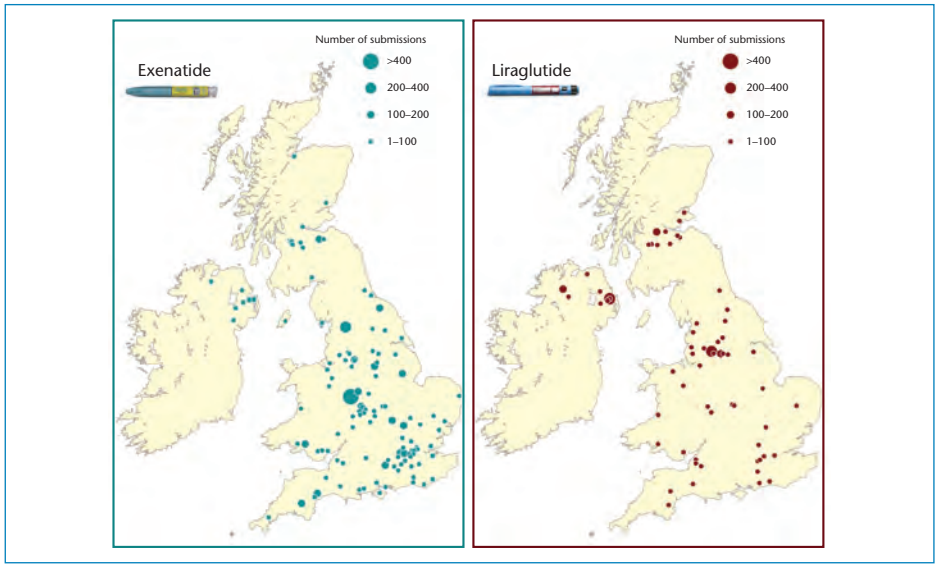

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Table 1: Baseline characteristics of patients in the ABCD nationwide exenatide and liraglutide audits.[4]

	Exenatide	Liraglutide
n	6717	2303 (from 3010)
Male (%)	54.9	54.1
Caucasian (%)	84.4	90.4
Age (years)	54.9 (10.6)	55.4 (11.2)
Diabetes duration (years)	8 (5–13)	9 (5–13)
HbA_{1c} (%)	9.47 (1.69)	9.32 (1.72)
Weight (kg)	113.8 (23.4)	111.1 (23.0)
BMI (kg/m^2)	39.8 (8.0)	39.1 (7.5)

Results with mean (SD) and median diabetes duration (inter-quartile range).

Data for the exenatide audit from Ryder REJ *et al.*; on behalf of the ABCD nationwide exenatide audit contributors. *Pract Diab Int* 2010; **27**: 352–7.

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Findings

The most noteworthy findings from Table 1 are the data showing that the patients entered had far worse glycaemic control and were much heavier in weight than patients treated in Phase III clinical trials of the two agents. Table 2 shows the data from the combined clinical trials alongside the mean baseline data from the ABCD audits. This difference in patients being treated with these agents in real clinical practice in the UK is perhaps not surprising when one considers that most of the prescribing of these new agents has been carried out by specialists in diabetes. The majority of patients with type 2 diabetes mellitus in the UK are treated in a primary care setting by non-specialist doctors who refer their more difficult-to-manage patients to specialists. It seems that the patients prescribed these agents, under the care of specialists, were particularly heavy in weight and were poorly controlled. The high mean body mass index (BMI) and HbA_{1c} may also have been influenced by prescribing guidelines in the UK, with the National Institute for Health and Clinical Excellence (NICE) recommending that in most instances exenatide and liraglutide should be restricted to patients with BMI $\geq$35.0 kg/m^2 and HbA_{1c} $\geq$7.5%.[5,6]

HbA_{1c} and weight changes

Figure 2 shows the mean HbA_{1c} and weight changes of patients at 3 and 6 months in the exenatide and liraglutide audits. It can be seen that by 6 months the mean HbA_{1c} had fallen by 0.75% in the exenatide audit, whereas in the liraglutide audit it had fallen by 0.93% and the difference between the audits was statistically significant. In contrast, by 6 months in the exenatide audit the mean weight had fallen by 6.5 kg, whereas it had

Table 2: Data comparing the baseline HbA_{1c} and BMI data of the combined clinical trials with that from the ABCD audits.

	Clinical trials combined	Real clinical use in UK (ABCD audit)
	Baseline HbA_{1c} (%)	
Exenatide	8.37	9.47
Liraglutide	8.50	9.32
	Baseline BMI (kg/m^2)	
Exenatide	32.7	39.8
Liraglutide	31.0	39.1

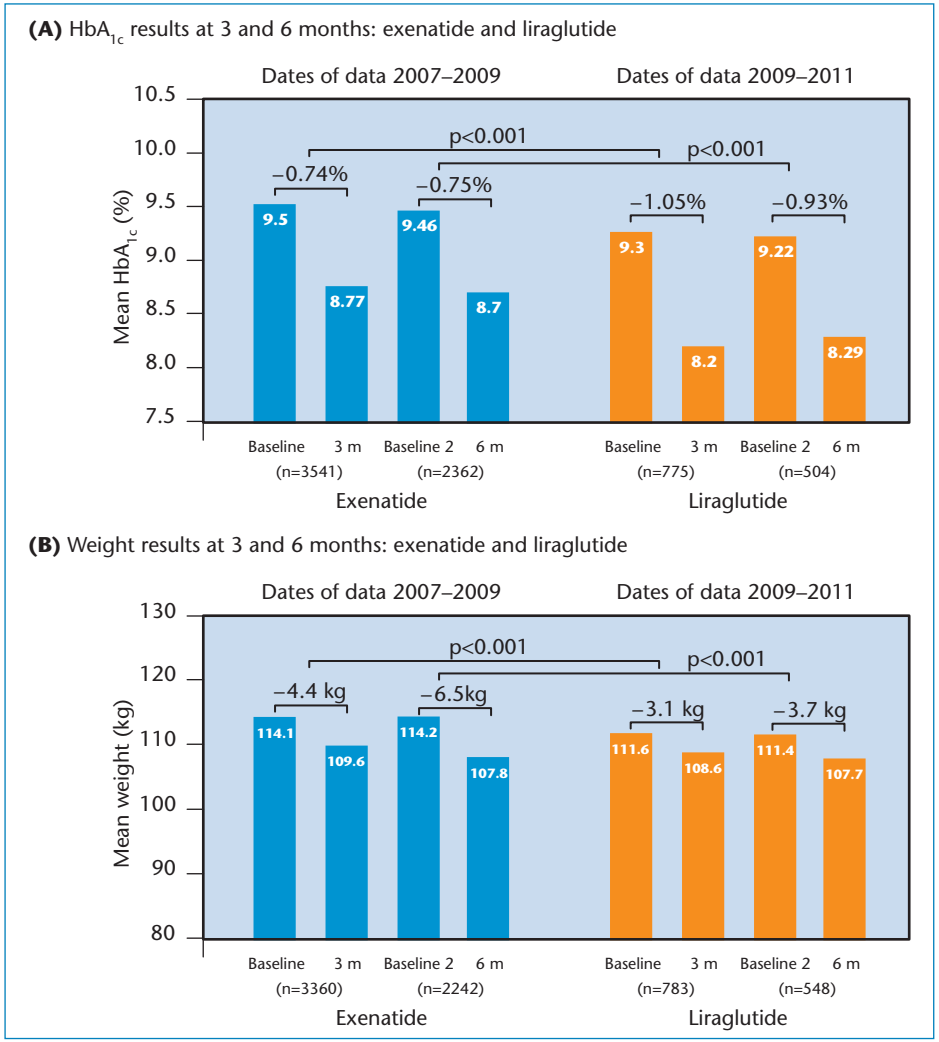
BMI: Body mass index.

fallen by 3.7 kg in the liraglutide audit and again the difference between the audits was statistically significant. Thus, patients appear to achieve a greater HbA_{1c} reduction but lesser weight reduction in the liraglutide audit as compared with the exenatide audit. However, it should be stressed that the data should not be looked at as if they were from a head-to-head clinical trial. We believe it is crucial to recognise that the exenatide data was collected between 2007 and 2009, whereas the liraglutide data used in the presentation was collected between 2009 and 2011. We believe that during the time of the introduction of GLP-1 receptor agonists in 2007, clinicians gradually learned over the 2 years that followed (the time of the exenatide audit) how to use this class of agent, and learning from experience changed their practice as they progressed. We suspect that much of the difference in the data from the two audits represents increasing confidence of clinicians with time in continuing and/or reducing other medications, in particular insulin, when using GLP-1 receptor agonists.

This is highlighted in Table 3. It can be seen that over a quarter of patients were on a thiazolidinedione (TZD) before exenatide was started and this was stopped in approximately half of these following initiation of exenatide therapy. Stopping TZD treatment is very likely to have reduced the mean reduction in HbA_{1c} at the same time as increasing the weight loss that occurred in the months ahead. By the time of the liraglutide audit 2 years later only about one in five patients were taking a TZD and, of these, fewer had it stopped – only about one in three. This would have avoided attenuating HbA_{1c} reduction and reduced the impact of weight loss with liraglutide treatment.

With regard to insulin, it can be seen that exenatide was used alongside insulin in a third of patients in the exenatide audit and, by the time of the liraglutide audit, confidence of specialists in using the combination of GLP-1 receptor agonists with insulin had increased such that it was used in ~40% of patients. At the time of the exenatide audit, approximately one in four patients on insulin when exenatide was started had their insulin stopped, whereas by the time of the liraglutide audit, confidence in the combination had increased such that only approximately 1 in 15 patients had their insulin stopped when liraglutide was started. Stopping insulin when initiating exenatide will have reduced the impact on HbA_{1c} of exenatide whilst improving weight loss.

Figure 2: HbA_{1c} and weight results at 3 and 6 months: exenatide and liraglutide audits.



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By contrast, the fact that more patients continued taking insulin during the liraglutide audit will have improved the impact of liraglutide on HbA_{1c} but reduced weight loss. Furthermore, with regard to insulin dose, if clinicians reduced the dose of insulin more during the time of the exenatide audit for fear of hypoglycaemia, this will also have resulted in less improvement on HbA_{1c} and more improvement on weight loss than during the time of the liraglutide audit when clinicians had learned to reduce the insulin by less in many cases.

Table 3: Baseline diabetes treatment use (and discontinuation) – exenatide and liraglutide audits.

	Exenatide	Liraglutide
Metformin	84.0 (0.9)	82.7 (0.7)
Sulphonylurea	49.5 (6.5)	42.8 (5.3)
Thiazolidinedione	27.1 (13.4)	20.5 (7.5)
Meglitinide	2.0 (0.6)	1.0 (0.2)
Acarbose	0.9 (0.3)	0.7 (0.3)
DPP-4 inhibitor	2.2 (1.4)	10.9 (9.3)
Exenatide	–	21.9 (21.9)
Insulin	33.9 (8.1)	39.6 (2.6)

Data represented as a percentage of 6717 and 3010 patients, respectively.

Ryder REJ, Thong K; ABCD nationwide exenatide and liraglutide audit contributors. ABCD nationwide exenatide and liraglutide audits. *Presented at the Diabetes UK Annual Professional Conference.* London, UK, 1 April 2011.

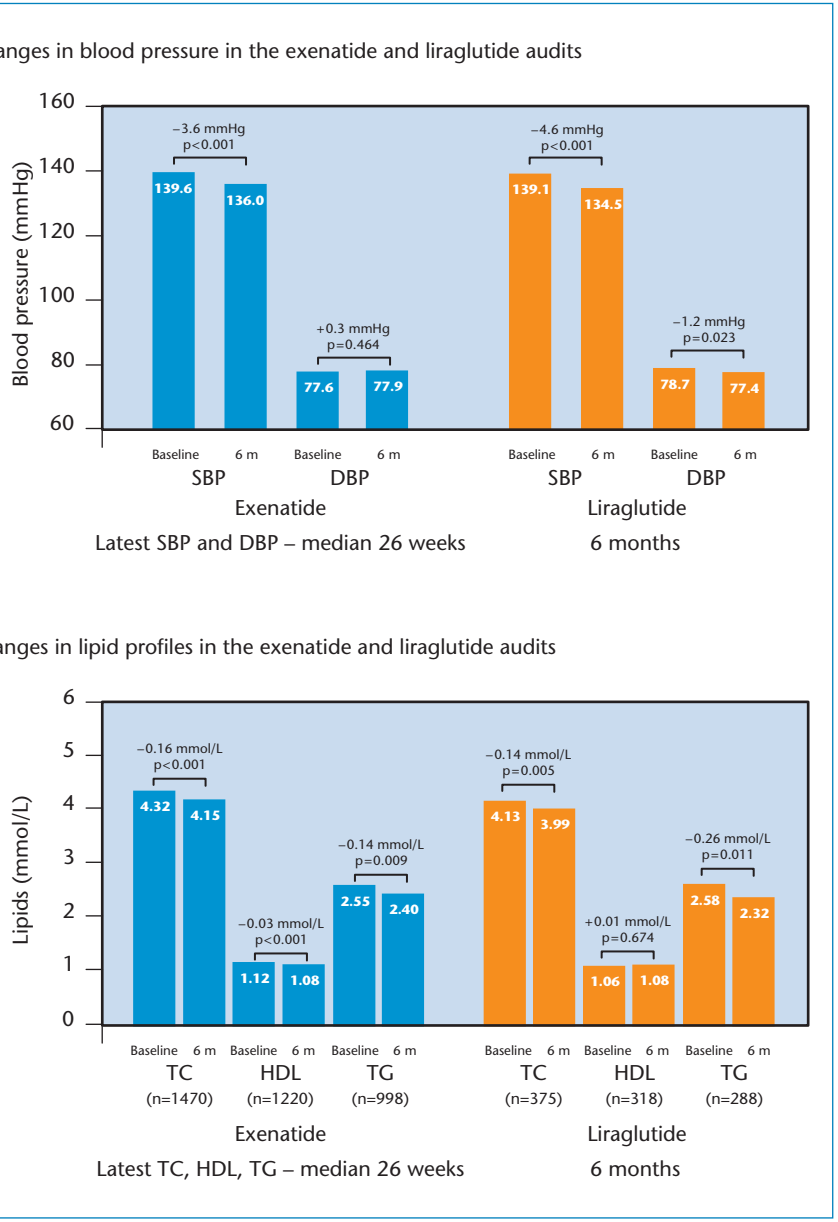
Blood pressure and lipids

Figure 3 shows the change in blood pressure and lipids in the two audits. It can be seen that there was lowering of systolic blood pressure, total cholesterol and triglycerides in both the exenatide and liraglutide audits, and that diastolic blood pressure was also lowered in the liraglutide audit. Treatments with exenatide and liraglutide were both associated with reductions in systolic blood pressure, total cholesterol and triglycerides, although the audits were not designed to evaluate concurrent changes in antihypertensives or lipid-lowering medications.

Adverse events

GI side effects were specifically requested in both audits. Table 4 shows a summary of adverse events. It is worth noting that GI side effects were reported in a little under a quarter of the patients in the exenatide audit, with 1 in 14 patients stopping exenatide permanently due to GI side effects,[4] and that GI side effects were reported less commonly in the liraglutide audit. With regard to pancreatitis (specifically requested in the exenatide audit but not in the liraglutide audit), four cases were reported from the exenatide audit, but after scrutiny three cases had alternative causes of pancreatitis, such as gallstones, significant alcohol consumption or significant hypertriglyceridaemia, and only in one case (a very mild case) was no obvious alternative cause found.[4] However, in the exenatide audit 14 cases of acute renal failure were reported: six cases were as a result of nausea and vomiting or diarrhoea leading to dehydration, four had a definite alternative cause, but there were four without an alternative cause for renal failure.[4] In the exenatide audit there were five cases of anaphylaxis.[4] Hypoglycaemia rates were higher in the exenatide audit, but hypoglycaemia was specifically asked for in the exenatide audit but not in the liraglutide audit.

Figure 3: Changes in blood pressure and lipid profiles in the exenatide and liraglutide audits.



DBP: Diastolic blood pressure; HDL: High-density lipoprotein; SBP: Systolic blood pressure; TC: Total cholesterol; TG: Triglyceride.

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Data for exenatide from Ryder REJ *et al.*; on behalf of the ABCD nationwide exenatide audit contributors. *Pract Diab Int* 2010; **27**: 352–7.

Table 4: Summary of adverse events in the exenatide and liraglutide audits.

Adverse event	Exenatide audit	Liraglutide audit	
Total GI side effects	23.7%	16.4%	2303 patients
Transient GI side effects	15.6%	9.9%	
Hypoglycaemia*	5.6%	1.0%	
Pancreatitis	4 cases (1 no alternate cause)	1 case	3010 patients
Acute renal failure	14 cases (0.2%)	1 case	
Headache	0.8%	0.4%	
Fatigue	0.5%	0.1%	
Dizziness	0.2%	0.2%	
Injection site problems	0.1%	0.2%	
Allergic reaction	0.2%	0.1%	
Thyroid	Not ascertained	1 benign thyroid adenoma	
Bleeding	Not ascertained	2 epistaxis, 1 GI, 1GU	
Raised LFT	Not ascertained	3 cases	

GI: Gastrointestinal; GU: Genitourinary; LFT: Liver function tests.

*Data on the occurrence of hypoglycaemia was specifically requested in the exenatide audit but not the liraglutide audit.

In both audits GI side effects were specifically asked for. Pancreatitis was specifically asked for in the exenatide but not the liraglutide audit.

Data for the exenatide audit from Ryder REJ *et al.*; on behalf of the ABCD nationwide exenatide audit contributors. *Pract Diab Int* 2010; **27**: 352–7.

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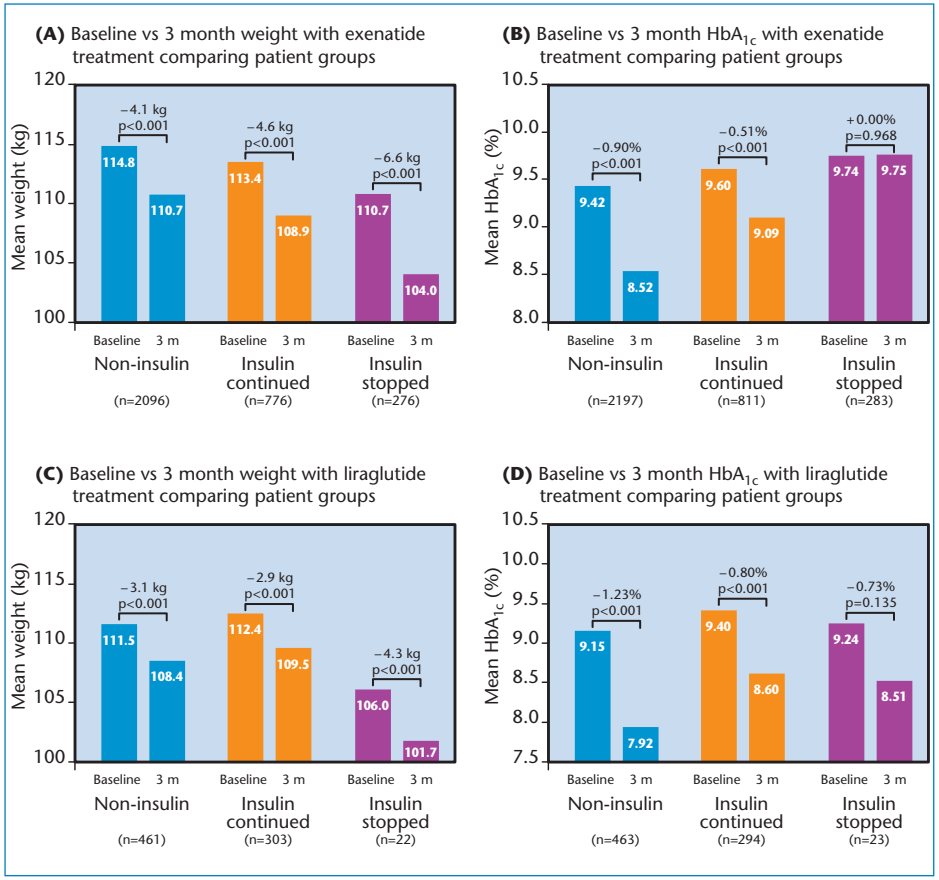
GLP-1 receptor agonist treatment with insulin

Figure 4 shows the HbA_{1c} and weight responses at 3 months, comparing patients who were not on insulin, patients who had their insulin continued at the time of starting exenatide or liraglutide, and patients who had their insulin stopped when starting exenatide or liraglutide. It can be seen that in both audits stopping insulin was associated with greater weight reduction but lesser impact on HbA_{1c} than continuing with insulin. As discussed earlier, we believe that the same differences between the two audits reflect the changing behaviour of clinicians as they grew confident in the use of the combination of insulin and GLP-1 receptor agonist and learned when they could, or could not, safely stop insulin and learned that there was no need to reduce the insulin dose by as much.

The problems of the learning phase during the exenatide audit are highlighted by the group of patients on exenatide in whom the insulin was stopped.[7] In this group the HbA_{1c} did not change between baseline and 3 months. The lack of change in mean HbA_{1c} shown in Figure 4B for the patients who stopped insulin, however, hid a great variability of response. Some patients responded well to exenatide with a reduction in HbA_{1c}, yet in others HbA_{1c} deteriorated considerably following cessation of insulin despite exenatide.[7] This ranged from an HbA_{1c} reduction of 7.3% to an increase of 5.5%.[7] Nearly 50% of patients had an increase in HbA_{1c} and in over a quarter this increase was ≥1%.[7] There were

Figure 4: Patient group comparisons of baseline vs 3 month weight and HbA_{1c} for exenatide and liraglutide treatment groups.[7]



Ryder REJ, Thong K; ABCD nationwide exenatide and liraglutide audit contributors. ABCD nationwide exenatide and liraglutide audits. *Presented at the Diabetes UK Annual Professional Conference*. London, UK, 1 April 2011.

11 reported cases of ketosis or diabetic ketoacidosis in the exenatide audit and seven of these occurred in patients who stopped insulin at the time of exenatide initiation.[7] Clinicians therefore learned that it could be dangerous to stop insulin at the time of exenatide initiation.[7] It can be seen from the data from the liraglutide audit that by the time of this audit this recommendation had been widely taken up. The data with regard to exenatide and insulin has been analysed in more detail.[7,8] It has been concluded that the impact on HbA_{1c} is less when exenatide is added to insulin-treated patients (mean [standard error] HbA_{1c} change: 0.94% (0.04) vs −0.51% (0.06) comparing non-insulin-treated patients with those who continued insulin).[8] Nevertheless, one in three patients in whom exenatide was added to insulin achieved an HbA_{1c} reduction of ≥1%.[8] One in six patients

managed to discontinue insulin whilst taking exenatide[8] and an insulin dose reduced from 1.0 ± 0.8 U/kg/day to 0.7 ± 0.7 U/kg/day ($p<0.001$). Hypoglycaemia with exenatide treatment was more frequent among insulin-treated patients (8.9 % vs 6.1%; $p<0.001$), and has been attributed to underlying insulin treatment rather than the addition of exenatide.[8]

Conclusion

Patients appear to achieve greater HbA_{1c} reduction but lesser weight reduction in the liraglutide audit as compared with the exenatide audit. However, there was lesser insulin and TZD discontinuation in the liraglutide audit. Contributors may have learnt from the previous use of exenatide to avoid over-reduction of diabetes treatment when initiating liraglutide. There was associated lowering of systolic blood pressure, total cholesterol and triglycerides with exenatide and liraglutide treatment. Lower diastolic blood pressure was associated with liraglutide treatment.

With regard to insulin, in the exenatide audit more than one third of insulin-treated patients achieved an HbA_{1c} reduction of ≥1%.[8] One in six discontinued insulin alongside HbA_{1c} reduction.[8] There was an insulin dose reduction from 1.0 ± 0.8 U/kg/day to 0.7 ± 0.7 U/kg/day ($p<0.001$).[8] There was no evidence of safety concerns despite higher rates of hypoglycaemia (from background insulin).[8] The combination of insulin plus exenatide was on average less effective and less well tolerated; however, a significant proportion of patients obtained significant benefit[8] and it is important not to stop insulin when starting exenatide – clinicians should aim to wean appropriate patients off insulin instead.[7]

Conflict of Interest

Dr Bob Ryder has received educational sponsorship, speaker fees and consultancy fees from a number of pharmaceutical companies, including Eli Lilly, GlaxoSmithKline, Novo Nordisk, Sanofi and Takeda.

Dr Ken Thong has received educational sponsorship from Eli Lilly, Novo Nordisk, Sanofi and Takeda.

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A list of ABCD nationwide exenatide and nationwide liraglutide audit contributors can be found in the appendix.

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The following are those whom we knew about at the DUK APC presentation on April 1, 2011.

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