ABCD nationwide audits of new diabetes therapies

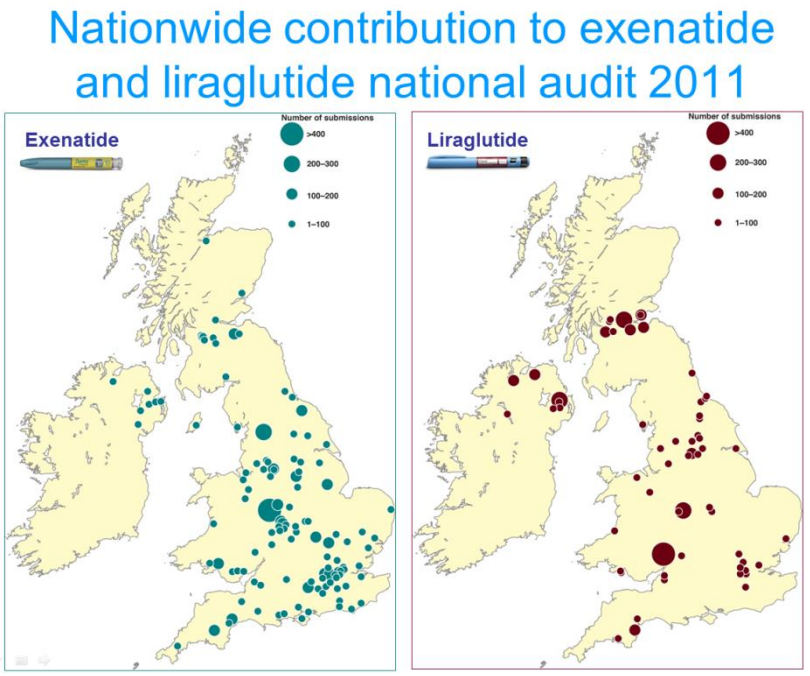
Dr Bob Ryder, ABCD Autumn Meeting

Royal College of Physicians

November 7, 2014

Association of British Clinical Diabetologists

ABCD nationwide exenatide and liraglutide audits



- Real-life data
  - >13000 patients from
  - >150 centres
  - >500 contributors
- There have been (by 2014)
  - 10 published papers
  - 23 abstracts
  - 13 oral presentations

http://www.diabetologists-abcd.org.uk/GLP1_Audits/PresentationsPostersAbstractsExenatide.htm
http://www.diabetologists-abcd.org.uk/GLP1_Audits/PresentationsPostersAbstractsLiraglutide.htm

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Acknowledgment

The ABCD nationwide exenatide audit is an independent audit supported by an unrestricted grant from Eli Lilly Ltd

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Acknowledgment
The ABCD nationwide liraglutide audit is an independent audit supported by an unrestricted grant from Novo Nordisk Ltd

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ABCD Nationwide Exenatide and Liraglutide Audits

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ABCD GLP1-RA audits v clinical trials

	Clinical trials combined	Real clinical use in UK (ABCD audit)
	Baseline HbA_{1c} (%)	
Exenatide	8.37	9.47
Liraglutide	8.5	9.40
	Baseline BMI (kg/m^2)	
Exenatide	32.72	39.8
Liraglutide	31	39.0

- The patients treated with GLP1-RAs in real clinical practice are much heavier and with much poorer glycaemic control than in clinical trials of these agents
- Nevertheless the agents have proven to be very effective

Ryder and Thong. In Hot topics in diabetes, 5th edition, Vora J, ed. Synergy, London, 2012: 49-61:
http://www.diabetologists-abcd.org.uk/GLP1_Audits/ABCD_Hot_Topics_2012.pdf

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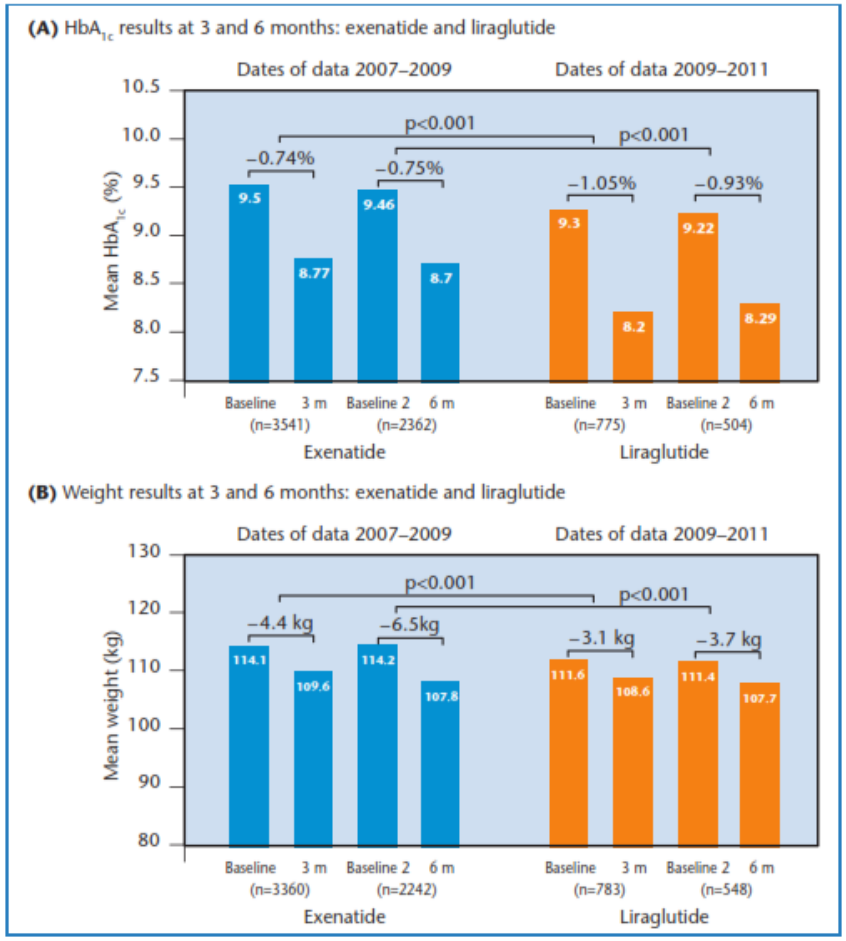
Difference in HbA1c and weight responses – exenatide v liraglutide audits



- Patients appear to achieve greater HbA1c reduction but lesser weight reduction in the liraglutide audit as compared with the exenatide audit
- However, there was much less insulin and TZD discontinuation in the liraglutide audit
- Contributors may have learnt from the previous use of exenatide (2007-2009) to avoid over-reduction of diabetes treatment when initiating liraglutide (2009-2011)

Ryder and Thong. In Hot topics in diabetes, 5th edition, Vora J, ed. Synergy, London, 2012: 49-61: http://www.diabetologists-abcd.org.uk/GLP1_Audits/ABCD_Hot_Topics_2012.pdf

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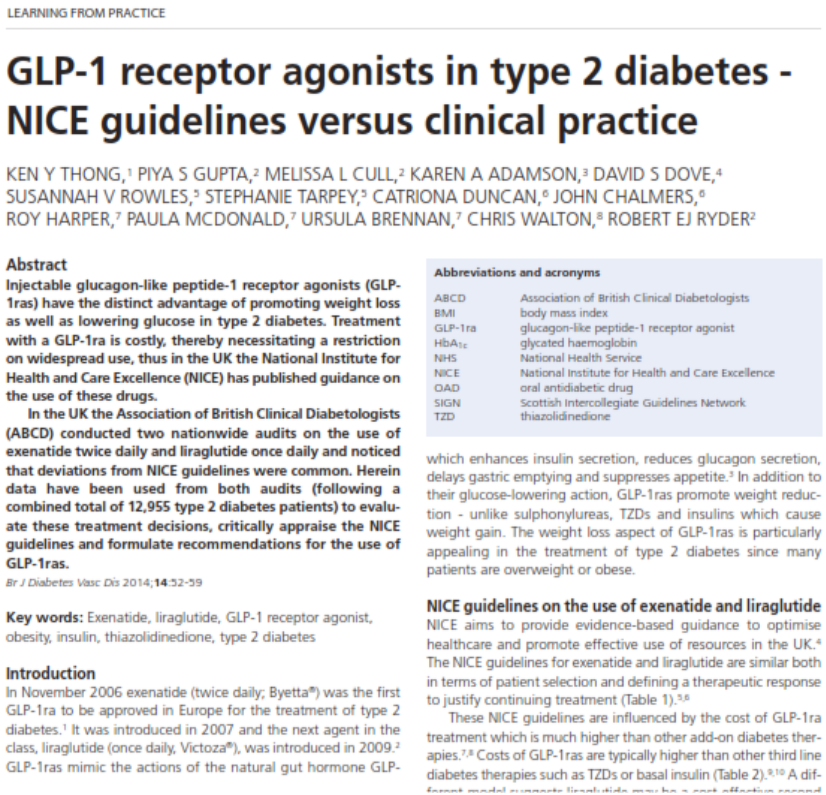
Reality versus NICE guidelines



LEARNING FROM PRACTICE

GLP-1 receptor agonists in type 2 diabetes - NICE guidelines versus clinical practice

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Abstract

Injectable glucagon-like peptide-1 receptor agonists (GLP-1ras) have the distinct advantage of promoting weight loss as well as lowering glucose in type 2 diabetes. Treatment with a GLP-1ra is costly, thereby necessitating a restriction on widespread use, thus in the UK the National Institute for Health and Care Excellence (NICE) has published guidance on the use of these drugs.

In the UK the Association of British Clinical Diabetologists (ABCD) conducted two nationwide audits on the use of exenatide twice daily and liraglutide once daily and noticed that deviations from NICE guidelines were common. Herein data have been used from both audits (following a combined total of 12,955 type 2 diabetes patients) to evaluate these treatment decisions, critically appraise the NICE guidelines and formulate recommendations for the use of GLP-1ras.

Br J Diabetes Vasc Dis 2014;**14**:52-59

Key words: Exenatide, liraglutide, GLP-1 receptor agonist, obesity, insulin, thiazolidinedione, type 2 diabetes

Abbreviations and acronyms

ABCD	Association of British Clinical Diabetologists
BMI	body mass index
GLP-1ra	glucagon-like peptide-1 receptor agonist
HbA_{1c}	glycated haemoglobin
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OAD	oral antidiabetic drug
SIGN	Scottish Intercollegiate Guidelines Network
TZD	thiazolidinedione

Introduction

In November 2006 exenatide (twice daily; Byetta®) was the first GLP-1ra to be approved in Europe for the treatment of type 2 diabetes.[1] It was introduced in 2007 and the next agent in the class, liraglutide (once daily, Victoza®), was introduced in 2009.[2] GLP-1ras mimic the actions of the natural gut hormone GLP-1, which enhances insulin secretion, reduces glucagon secretion, delays gastric emptying and suppresses appetite.[3] In addition to their glucose-lowering action, GLP-1ras promote weight reduction - unlike sulphonylureas, TZDs and insulins which cause weight gain. The weight loss aspect of GLP-1ras is particularly appealing in the treatment of type 2 diabetes since many patients are overweight or obese.

NICE guidelines on the use of exenatide and liraglutide

NICE aims to provide evidence-based guidance to optimise healthcare and promote effective use of resources in the UK.[4] The NICE guidelines for exenatide and liraglutide are similar both in terms of patient selection and defining a therapeutic response to justify continuing treatment (Table 1).[5,6]

These NICE guidelines are influenced by the cost of GLP-1ra treatment which is much higher than other add-on diabetes therapies.[7,8] Costs of GLP-1ras are typically higher than other third line diabetes therapies such as TZDs or basal insulin (Table 2).[9,10] A dif-

- Exenatide and liraglutide used outside NICE guidelines in substantial numbers of patients
- Proven effective in outside NICE guidelines
- In particular used with insulin (40% in the nationwide liraglutide audit) with good effect in many patients
- The NICE 6 month weight loss (≥ 3% initial body weight) and HbA1c fall (≥ 1%) criteria are too restrictive by not taking into account the diversity of patients and their responses which can be much more one criterion than the other

Thong et al. Br J Diabetes Vasc Dis 2014; 14: 52-59

Association of British Clinical Diabetologists

Off licence use with insulin

original article

Diabetes, Obesity and Metabolism 13: 703–710, 2011.

Safety, efficacy and tolerability of exenatide in combination with insulin in the Association of British Clinical Diabetologists nationwide exenatide audit*

K. Y. Thong[1], B. Jose[1], N. Sukumar[1], M. L. Cull[1], A. P. Mills[1], T. Sathyapalan[2], W. Shafiq[2], A. S. Rigby[2], C. Walton[2] & R. E. J. Ryder[1] on behalf of the ABCD nationwide exenatide audit contributors†

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ORIGINAL ARTICLE

Aim: To assess the extent, safety, efficacy and tolerability of reported off-licence exenatide use through a nationwide audit.
Methods: The Association of British Clinical Diabetologists hosted a password-protected, online collection of anonymized data of exenatide use in real clinical practice. Three hundred and fifteen contributors from 126 centres across UK provided data on 6717 patients. HbA1c and weight changes, exenatide discontinuation, adverse events and treatment satisfaction were compared between non-insulin and insulin-treated patients.
Results: Four thousand eight hundred and fifty-seven patients had baseline and follow-up treatment status with mean (±s.d.) baseline HbA1c 9.45 ± 1.69% and BMI 40.0 ± 8.2 kg/m^2. Of the 4857 patients, 1921 (39.6%) used exenatide with insulin. Comparing patients who continued insulin with exenatide with non-insulin-treated patients, mean (±s.e.) latest HbA1c and weight reduction (median 26 weeks) were 0.51 ± 0.06 versus 0.94 ± 0.04% ($p < 0.001$) and 5.8 ± 0.2 versus 5.5 ± 0.1 kg ($p = 0.278$). Insulin-treated patients had higher rates of exenatide discontinuation (31.0 vs. 13.9%, $p < 0.001$), hypoglycaemia (8.9 vs. 6.1%, $p < 0.001$), gastrointestinal side effects (28.4 vs. 25.0%, $p = 0.008$) and treatment dissatisfaction (20.8 vs. 5.7%, $p < 0.001$). However, 34.2% of the patients continuing insulin still achieved HbA1c reduction ≥1%. There was significant insulin discontinuation, dose reduction and greater sulphonylurea discontinuation among insulin-treated patients.
Conclusions: Addition of exenatide to obese, insulin-treated patients can improve glycaemia and weight. Adverse events were statistically but probably not clinically significantly higher, but combination treatment was less well tolerated. Overall, exenatide was less effective in lowering HbA1c among insulin-treated patients, although significant number of insulin-treated patients still achieved significant HbA1c, weight and insulin reductions. Further research into identifying obese, insulin-treated patients who will tolerate and benefit from exenatide treatment is urgently needed.
Keywords: exenatide, GLP-1 analogue, incretin therapy, insulin therapy, type 2 diabetes

Date submitted 29 December 2010; date of first decision 7 February 2011; date of final acceptance 9 March 2011

- Off licence exenatide with insulin safe and effective in real clinical practice
- Reduction in insulin dose frequently occurred
- Weight fell
- 1 in 6 patients came off insulin

Thong et al. Diabetes, Obesity and Metabolism 2011; 13(8): 703-710

Association of British Clinical Diabetologists

An important safety issue uncovered

DIABETES RESEARCH AND CLINICAL PRACTICE 93 (2011) e87–e91

Contents lists available at ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres

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International Diabetes Federation

Brief report

Response at 3 months to insulin dose decisions made at exenatide initiation in the Association of British Clinical Diabetologists (ABCD) nationwide exenatide audit

K.Y. Thong [a,1,*], B. Jose [a,1], A.D. Blann [a,1], M.L. Cull [a,1], A.P. Mills [a,1], T. Sathyapalan [b,1], C. Walton [b,1], R.E.J. Ryder [a,1]

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ARTICLE INFO

Article history:
Received 20 February 2011
Received in revised form
12 April 2011
Accepted 5 May 2011
Published on line 1 June 2011

Keywords:
Exenatide
GLP-1 agonist
Insulin treatment
Obesity
Type 2 diabetes

ABSTRACT

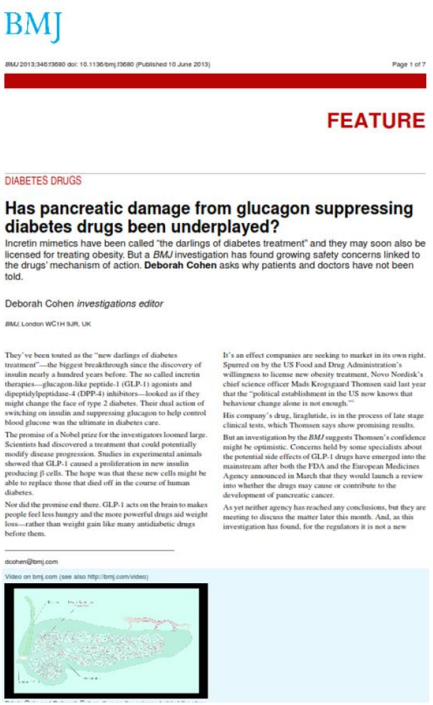
It is uncertain what should be done with insulin dose if starting exenatide. In the ABCD nationwide exenatide audit, many patients with type 2 diabetes had worsened glycaemia when insulin was stopped. If starting exenatide, insulin should not be stopped but weaned off only if there is significant glycaemic response.

- Some clinicians attempted to stop insulin when starting exenatide in order to stay within guidelines
- This led to harm to the patient in some instances
- For example there are 11 reported cases of ketosis or diabetic ketoacidosis - 7 of these occurred to patients who stopped insulin at the time of exenatide initiation
- Analysis of audit data allowed us to recommend that when starting a GLP1-RA in an insulin-treated patient not to stop the insulin but rather to tail the insulin off during treatment if response to treatment allowed

Thong et al. Diabetes Res Clin Pract. 2011; 93(2): e87-e91

ABCD
Association of British Clinical Diabetologists

Pancreatitis



BMJ

BMJ 2013;346:f3680 doi: 10.1136/bmj.f3680 (Published 10 June 2013) Page 1 of 7

FEATURE

DIABETES DRUGS

Has pancreatic damage from glucagon suppressing diabetes drugs been underplayed?

Incretin mimetics have been called "the darlings of diabetes treatment" and they may soon also be licensed for treating obesity. But a *BMJ* investigation has found growing safety concerns linked to the drugs' mechanism of action. **Deborah Cohen** asks why patients and doctors have not been told.

Deborah Cohen *investigations editor*

BMJ, London WC1H 9JR, UK

They've been touted as the "new darlings of diabetes treatment"—the biggest breakthrough since the discovery of insulin nearly a hundred years before. The so called incretin therapies—glucagon-like peptide-1 (GLP-1) agonists and dipeptidylpeptidase-4 (DPP-4) inhibitors—looked as if they might change the face of type 2 diabetes. Their dual action of switching on insulin and suppressing glucagon to help control blood glucose was the ultimate in diabetes care.

The promise of a Nobel prize for the investigators loomed large. Scientists had discovered a treatment that could potentially modify disease progression. Studies in experimental animals showed that GLP-1 caused a proliferation in new insulin producing β cells. The hope was that these new cells might be able to replace those that died off in the course of human diabetes.

Nor did the promise end there. GLP-1 acts on the brain to makes people feel less hungry and the more powerful drugs aid weight loss—rather than weight gain like many antidiabetic drugs before them.

It's an effect companies are seeking to market in its own right. Spurred on by the US Food and Drug Administration's willingness to license new obesity treatment, Novo Nordisk's chief science officer Mads Krogsgaard Thomsen said last year that the "political establishment in the US now knows that behaviour change alone is not enough."

His company's drug, liraglutide, is in the process of late stage clinical tests, which Thomsen says show promising results.

But an investigation by the *BMJ* suggests Thomsen's confidence might be optimistic. Concerns held by some specialists about the potential side effects of GLP-1 drugs have emerged into the mainstream after both the FDA and the European Medicines Agency announced in March that they would launch a review into whether the drugs may cause or contribute to the development of pancreatic cancer.

As yet neither agency has reached any conclusions, but they are meeting to discuss the matter later this month. And, as this investigation has found, for the regulators it is not a new

dcohen@bmj.com

Video on bmj.com (see also http://bmj.com/video)

Cohen D. Br Med J 2013; 346: f3680

- Alarm raised (BMJ and Channel 4 Dispatches TV programme) in 2013 that incretin therapies might cause pancreatic damage
- We have been able to contribute by publishing data suggesting that in the ABCD audits there is no evidence of such a side effect:

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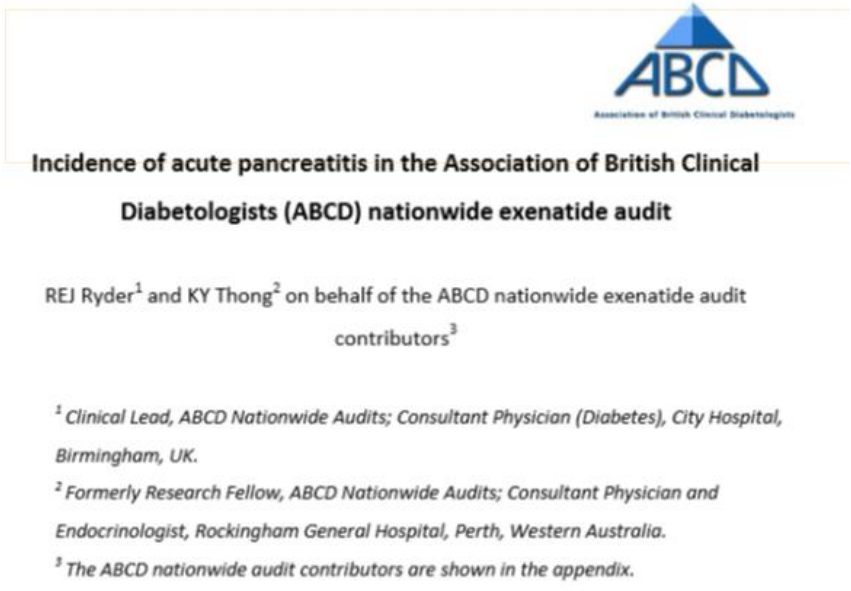
Rates of acute pancreatitis in people with type 2 diabetes



Incidence of acute pancreatitis in the Association of British Clinical Diabetologists (ABCD) nationwide exenatide audit

REJ Ryder[1] and KY Thong[2] on behalf of the ABCD nationwide exenatide audit contributors[3]

[1] *Clinical Lead, ABCD Nationwide Audits; Consultant Physician (Diabetes), City Hospital, Birmingham, UK.*

[2] *Formerly Research Fellow, ABCD Nationwide Audits; Consultant Physician and Endocrinologist, Rockingham General Hospital, Perth, Western Australia.*

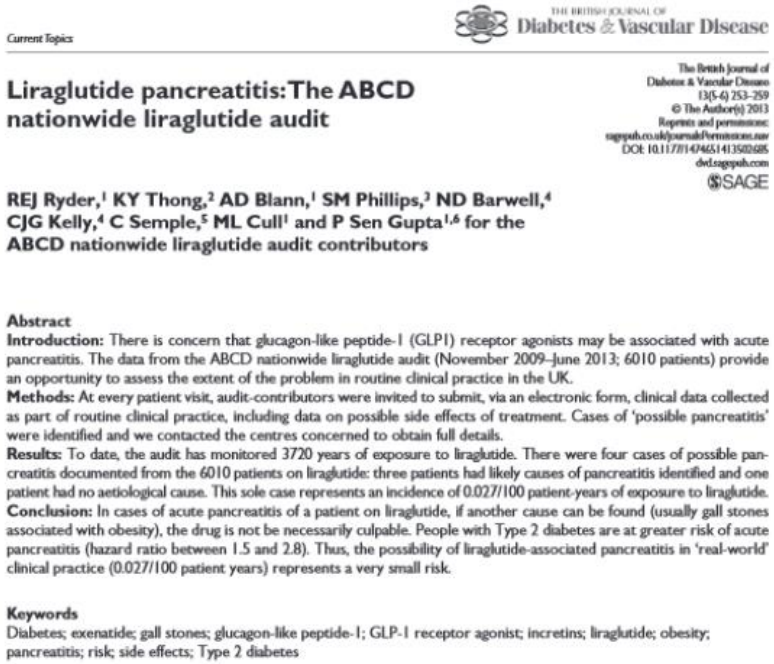
[3] *The ABCD nationwide audit contributors are shown in the appendix.*

- Not on GLP-1 based therapy:
  - between 5 and 56 per 10,000 person years
- ABCD nationwide exenatide audit
  - 12 per 10,000 person year
- ABCD nationwide liraglutide audit
  - 10.8 per 10,000 person years

http://www.diabetologists-abcd.org.uk/GLP1_Audits/pancreatitis_incidence_exenatide_audit.pdf

Association of British Clinical Diabetologists

Rates of acute pancreatitis in people with type 2 diabetes



Current Topics

THE BRITISH JOURNAL OF Diabetes & Vascular Disease

Liraglutide pancreatitis: The ABCD nationwide liraglutide audit

The British Journal of Diabetes & Vascular Disease
13(5-6) 253–259
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sagepub.co.uk/journalsPermissions.nav
DOI: 10.1177/1474651413502685
dvd.sagepub.com
SAGE

REJ Ryder,[1] KY Thong,[2] AD Blann,[1] SM Phillips,[3] ND Barwell,[4] CJG Kelly,[4] C Semple,[5] ML Cull[1] and P Sen Gupta[1,6] for the ABCD nationwide liraglutide audit contributors

Abstract

Introduction: There is concern that glucagon-like peptide-1 (GLP1) receptor agonists may be associated with acute pancreatitis. The data from the ABCD nationwide liraglutide audit (November 2009–June 2013; 6010 patients) provide an opportunity to assess the extent of the problem in routine clinical practice in the UK.

Methods: At every patient visit, audit-contributors were invited to submit, via an electronic form, clinical data collected as part of routine clinical practice, including data on possible side effects of treatment. Cases of 'possible pancreatitis' were identified and we contacted the centres concerned to obtain full details.

Results: To date, the audit has monitored 3720 years of exposure to liraglutide. There were four cases of possible pancreatitis documented from the 6010 patients on liraglutide: three patients had likely causes of pancreatitis identified and one patient had no aetiological cause. This sole case represents an incidence of 0.027/100 patient-years of exposure to liraglutide.

Conclusion: In cases of acute pancreatitis of a patient on liraglutide, if another cause can be found (usually gall stones associated with obesity), the drug is not be necessarily culpable. People with Type 2 diabetes are at greater risk of acute pancreatitis (hazard ratio between 1.5 and 2.8). Thus, the possibility of liraglutide-associated pancreatitis in 'real-world' clinical practice (0.027/100 patient years) represents a very small risk.

Keywords

Diabetes; exenatide; gall stones; glucagon-like peptide-1; GLP-1 receptor agonist; incretins; liraglutide; obesity; pancreatitis; risk; side effects; Type 2 diabetes

- Rates of acute pancreatitis in the ABCD exenatide and liraglutide audits are at the low end of the rates expected for people with type 2 diabetes in general.

AND

- 75% of the cases of acute pancreatitis in the ABCD exenatide and liraglutide audits had other causes for acute pancreatitis, in particular gall bladder disease

Ryder and Thong. Br J Diabetes Vasc Dis 2013; 13: 253-259

ABCD
Association of British Clinical Diabetologists

Otherwise unexplained pancreatitis – is it likely to be due to the GLP-1RA?

DOI: 10.1111/dme.12336

The Association of British Clinical Diabetologists nationwide exenatide and liraglutide audits suggest a low incidence of acute pancreatitis. Response to Robson. Incretins and pancreatitis—what happens next? A personal viewpoint

Diabet. Med. 30, 1510–1511 (2013)

We are concerned that Dr Robson [1] has concluded erroneously that rates of acute pancreatitis from the Association of British Clinical Diabetologists (ABCD) nationwide exenatide and liraglutide audits are 'higher than expected' [1]. For the exenatide audit, the pancreatitis rate was 12/10 000 person years [2] and, for the liraglutide audit, 10.8/10 000 person years [3]. These audits combined contain data on 12 727 'real-world' UK patients with Type 2 diabetes treated with the respective glucagon-like peptide 1 (GLP-1) receptor agonist. In interpreting acute pancreatitis rates as he has, Dr Robson has failed to acknowledge that people with Type 2 diabetes in general (i.e. not on GLP-1-based therapies) are at greater risk of acute pancreatitis (hazard ratio between 1.5 and 2.8 [4–6]) than people without diabetes. The rates of acute pancreatitis in people with Type 2 diabetes not on GLP-1-based therapies are between 5 and 56/10 000 person years [4–7]. Thus, the rates of acute pancreatitis in the ABCD British Clinical Diabetologists audit would be of concern. Adverse event rates of 6/10 000 per year are comparable with that of the highest estimates of rhabdomyolysis in high-intensity statins, or the risk of deep vein thrombosis with third-generation oral contraceptives'. We believe that Dr Robson's conclusion is highly misleading, given that the rate of 11–12/10 000 person years is in fact low for people with Type 2 diabetes.

Finally, Dr Robson mentions increased hypoglycaemia amongst patients treated with exenatide in the ABCD exenatide audit [1]. This hypoglycaemia was testimony to the glycaemic efficacy of exenatide when added to insulin or sulphonylureas. It is attributable to the insulin and sulphonylureas, and resolves as the latter agents are reduced or stopped.

Funding sources

The ABCD nationwide exenatide and liraglutide audit programme has received grants from Eli Lilly and Novo Nordisk. These audits were independently initiated and performed by ABCD. ABCD remained independent in undertaking the audits and in analysing and reporting the data.

Competing interests

REJR has received speaker fees, consultancy fees and/or educational sponsorships from a number of companies, including Bristol Myers Squibb/Astra Zeneca Alliance, Eli Lilly, GlaxoSmithKline, Novo Nordisk, Sanofi-Aventis and Takeda. PSG has received speaker fees from Eli Lilly and educational sponsorship from Bristol Myers Squibb,

*The exenatide audit contributors are listed in reference 2.
†The liraglutide audit contributors are listed in reference 3.

- ….it is worth remembering that many cases of acute pancreatitis are "idiopathic" ….
- ….hence exenatide or liraglutide may not be the actual cause even if no other cause is found

Ryder et al. Diabetic Medicine 2013; 30(12): 1510-1511

ABCD
Association of British Clinical Diabetologists

GLP1-RAs in professional drivers

Insulin avoidance and treatment outcomes among patients with a professional driving licence starting glucagon-like peptide 1 (GLP-1) agonists in the Association of British Clinical Diabetologists (ABCD) nationwide exenatide and liraglutide audits

Diabet. Med. 29, 690–692 (2012)

Mainly as a result of the concerns regarding hypoglycaemia and the risk to public safety, most persons with insulin-treated diabetes are ineligible to obtain a Group 2 vehicle licence. As defined by the Driver and Vehicle Licensing Agency (DVLA), Group 2 vehicles include large goods vehicles (such as lorries) and passenger carrying vehicles (such as buses). They do not include taxis or emergency vehicles (such as police vehicles or ambulance), although it has been recommended that similar medical standards be applied (see also Supporting Information, Appendix S1) [1,2].

Treatment for Type 2 diabetes with the glucagon-like peptide (GLP-1) agonists exenatide and liraglutide is associated with weight loss and a low hypoglycaemia risk [3,4]. The Driver and Vehicle Licensing Agency raises no specific caution to the use of GLP-1 agonists unless used concurrently with a sulphonylurea [1]. Guidelines by the National Institute for Health and Clinical Excellence (NICE) list GLP-1 agonists as alternatives to insulin when a patient's occupation is significantly affected by insulin use. This was beyond the usual treatment indication in patients with suboptimal control and a BMI ≥ 35 kg/m^2 [5,6].

The Association of British Clinical Diabetologists (ABCD) conducted two nationwide audits on the use of exenatide, and liraglutide, based in clinical practice. The exenatide audit

more had a BMI of < 35 kg/m^2 (46.2 vs. 29.1%, $P < 0.001$). To compare outcomes, we matched professional drivers with other audit patients with similar baseline characteristics and duration of follow-up (Table 1).

When compared with other matched patients, professional drivers were less likely to be on insulin at baseline (14.6 vs. 34.8%, $P < 0.001$), while those on insulin were much more likely to stop insulin after GLP-1 agonist treatment (50.0 vs. 28.6%, $P = 0.004$). In contrast, they were more likely to be on three oral hypoglycaemic agents (34.0 v 17.8%, $P < 0.001$), including more frequent sulphonylurea use (72.0 vs. 47.9%, $P < 0.001$). The Driver and Vehicle Licensing Agency identifies treatment with sulphonylurea as a hypoglycaemia risk, but not a reason to disallow a Group 2 licence.

At 6 months, professional drivers achieved similar treatment responses when compared with matched counterparts. Mean (± SE) HbA_{1c} reductions were −10 mmol/mol (± 2) [−0.91% (± 0.16)] vs. −10 mmol/mol (± 0) [−0.88% (± 0.04)] (difference, $P = 0.862$). Weight reductions were −4.7 kg (± 0.4) vs. −4.3 kg (± 0.1) (difference, $P = 0.259$). At median follow-ups of 40 and 37 weeks, hypoglycaemia (defined by individual centres) was reported in 6.7 and 4.0% in each group, respectively ($P = 0.027$). No cases of hypoglycaemia requiring third-party assistance were reported among professional drivers. In the same time period, rates of GLP-1 agonist discontinuation were similar; 15.2 vs. 17.4% ($P = 0.349$).

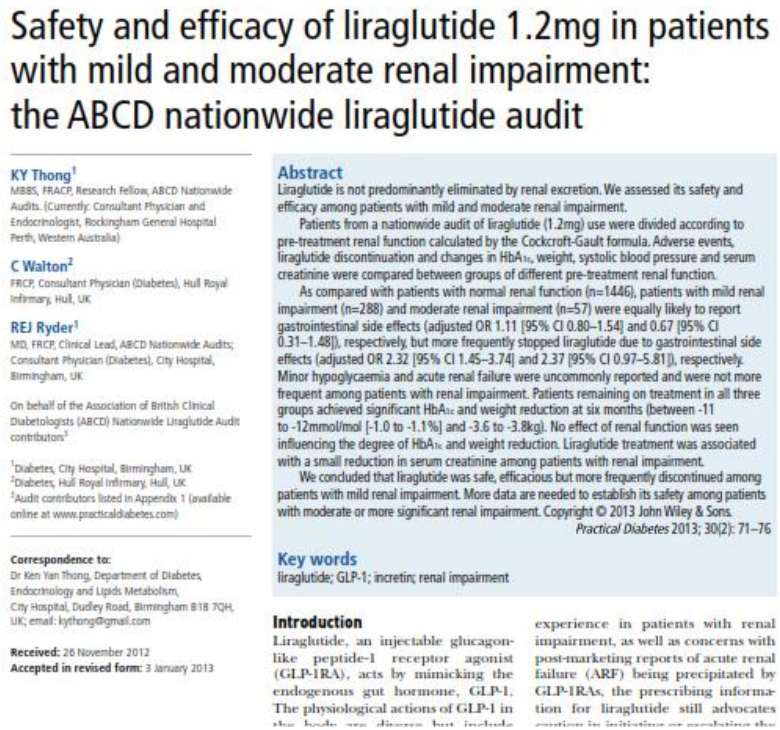
The audits demonstrated clear benefits of GLP-1 agonist treatment on glycaemia and weight among patients with a driving occupation affected by insulin use. Hypoglycaemia was infrequent, although slightly more common among professional drivers, possibly because of a higher rate of sulphonylurea use.

- Many patients with a professional drivers licence who would lose their jobs if they went onto insulin, have been able to avoid insulin, and maintain similar glycaemic outcomes and keep their jobs by using exenatide or liraglutide

Thong et al. Diabetic Medicine 2012; 29(5): 690-692

Association of British Clinical Diabetologists

Liraglutide in renal impairment



Safety and efficacy of liraglutide 1.2mg in patients with mild and moderate renal impairment: the ABCD nationwide liraglutide audit

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On behalf of the Association of British Clinical Diabetologists (ABCD) Nationwide Liraglutide Audit contributors[3]

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[2]Diabetes, Hull Royal Infirmary, Hull, UK
[3]Audit contributors listed in Appendix 1 (available online at www.practicaldiabetes.com)

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Received: 26 November 2012
Accepted in revised form: 3 January 2013

Abstract

Liraglutide is not predominantly eliminated by renal excretion. We assessed its safety and efficacy among patients with mild and moderate renal impairment.

Patients from a nationwide audit of liraglutide (1.2mg) use were divided according to pre-treatment renal function calculated by the Cockcroft-Gault formula. Adverse events, liraglutide discontinuation and changes in HbA_{1c}, weight, systolic blood pressure and serum creatinine were compared between groups of different pre-treatment renal function.

As compared with patients with normal renal function (n=1446), patients with mild renal impairment (n=288) and moderate renal impairment (n=57) were equally likely to report gastrointestinal side effects (adjusted OR 1.11 [95% CI 0.80–1.54] and 0.67 [95% CI 0.31–1.48]), respectively, but more frequently stopped liraglutide due to gastrointestinal side effects (adjusted OR 2.32 [95% CI 1.45–3.74] and 2.37 [95% CI 0.97–5.81]), respectively. Minor hypoglycaemia and acute renal failure were uncommonly reported and were not more frequent among patients with renal impairment. Patients remaining on treatment in all three groups achieved significant HbA_{1c} and weight reduction at six months (between -11 to -12mmol/mol [-1.0 to -1.1%] and -3.6 to -3.8kg). No effect of renal function was seen influencing the degree of HbA_{1c} and weight reduction. Liraglutide treatment was associated with a small reduction in serum creatinine among patients with renal impairment.

We concluded that liraglutide was safe, efficacious but more frequently discontinued among patients with mild renal impairment. More data are needed to establish its safety among patients with moderate or more significant renal impairment.

Practical Diabetes 2013; 30(2): 71–76

Key words
liraglutide; GLP-1; incretin; renal impairment

Introduction

Liraglutide, an injectable glucagon-like peptide-1 receptor agonist (GLP-1RA), acts by mimicking the endogenous gut hormone, GLP-1. The physiological actions of GLP-1 in

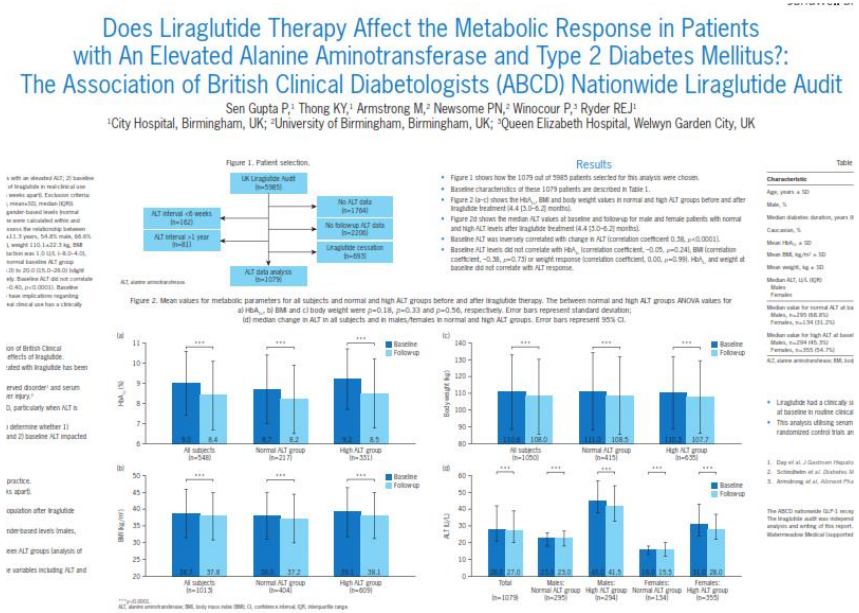
experience in patients with renal impairment, as well as concerns with post-marketing reports of acute renal failure (ARF) being precipitated by GLP-1RAs, the prescribing informa-tion for liraglutide still advocates

- Liraglutide was safe and effective among patients with moderate renal impairment, which has been an exclusion for use

Thong et al. Practical Diabetes 2013; 30(2): 71-76

Association of British Clinical Diabetologists

Diabetes and NAFLD – impact on ALT



Does Liraglutide Therapy Affect the Metabolic Response in Patients with An Elevated Alanine Aminotransferase and Type 2 Diabetes Mellitus?: The Association of British Clinical Diabetologists (ABCD) Nationwide Liraglutide Audit

Sen Gupta P,[1] Thong KY,[1] Armstrong M,[2] Newsome PN,[2] Winocour P,[3] Ryder REJ[1]

[1]City Hospital, Birmingham, UK; [2]University of Birmingham, Birmingham, UK; [3]Queen Elizabeth Hospital, Welwyn Garden City, UK

Figure 1. Patient selection.

Results

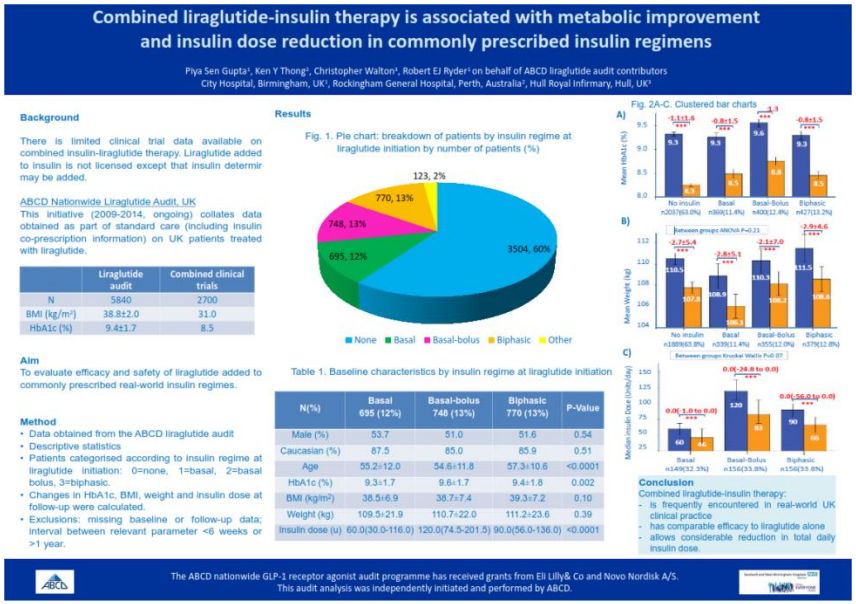
Figure 2. Mean values for metabolic parameters for all subjects and normal and high ALT groups before and after liraglutide therapy.

- Liraglutide can reduce ALT when it is elevated – ALT being an index of fat in the liver ….

Sen Gupta et al. Diabetes 2013; 62 (Suppl. 1): 1037P

Association of British Clinical Diabetologists

Liraglutide with different insulin regimes



Combined liraglutide-insulin therapy is associated with metabolic improvement and insulin dose reduction in commonly prescribed insulin regimens

Piya Sen Gupta[1], Ken Y Thong[2], Christopher Walton[1], Robert EJ Ryder[1] on behalf of ABCD liraglutide audit contributors
City Hospital, Birmingham, UK[1], Rockingham General Hospital, Perth, Australia[2], Hull Royal Infirmary, Hull, UK[3]

Background

There is limited clinical trial data available on combined insulin-liraglutide therapy. Liraglutide added to insulin is not licensed except that insulin determir may be added.

ABCD Nationwide Liraglutide Audit, UK
This initiative (2009-2014, ongoing) collates data obtained as part of standard care (including insulin co-prescription information) on UK patients treated with liraglutide.

	Liraglutide audit	Combined clinical trials
N	5840	2700
BMI (kg/m²)	38.8±2.0	31.0
HbA1c (%)	9.4±1.7	8.5

Aim
To evaluate efficacy and safety of liraglutide added to commonly prescribed real-world insulin regimes.

Method
- Data obtained from the ABCD liraglutide audit
- Descriptive statistics
- Patients categorised according to insulin regime at liraglutide initiation: 0=none, 1=basal, 2=basal bolus, 3=biphasic.
- Changes in HbA1c, BMI, weight and insulin dose at follow-up were calculated.
- Exclusions: missing baseline or follow-up data; interval between relevant parameter <6 weeks or >1 year.

Results

Fig. 1. Pie chart: breakdown of patients by insulin regime at liraglutide initiation by number of patients (%)

Table 1. Baseline characteristics by insulin regime at liraglutide initiation

N(%)	Basal 695 (12%)	Basal-bolus 748 (13%)	Biphasic 770 (13%)	P-Value
Male (%)	53.7	51.0	51.6	0.54
Caucasian (%)	87.5	85.0	85.9	0.51
Age	55.2±12.0	54.6±11.8	57.3±10.6	<0.0001
HbA1c (%)	9.3±1.7	9.6±1.7	9.4±1.8	0.002
BMI (kg/m²)	38.5±6.9	38.7±7.4	39.3±7.2	0.10
Weight (kg)	109.5±21.9	110.7±22.0	111.2±23.6	0.39
Insulin dose (u)	60.0(30.0-116.0)	120.0(74.5-201.5)	90.0(56.0-136.0)	<0.0001

Fig. 2A-C. Clustered bar charts

Conclusion
Combined liraglutide-insulin therapy:
- is frequently encountered in real-world UK clinical practice
- has comparable efficacy to liraglutide alone
- allows considerable reduction in total daily insulin dose.

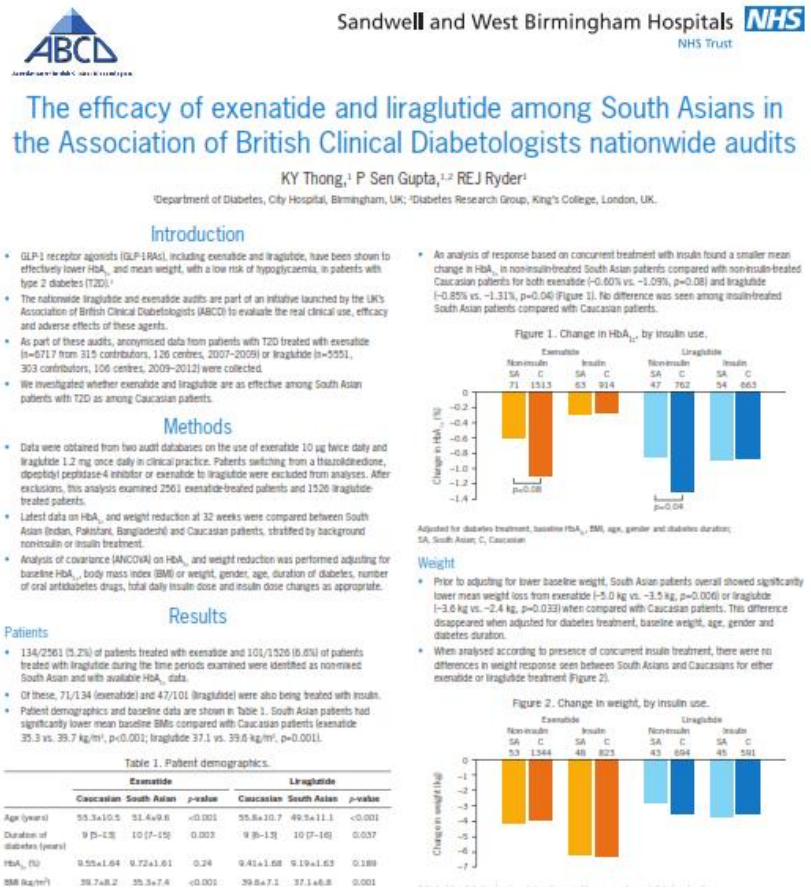
The ABCD nationwide GLP-1 receptor agonist audit programme has received grants from Eli Lilly& Co and Novo Nordisk A/S.
This audit analysis was independently initiated and performed by ABCD.

- Liraglutide was effective with all the common insulin regimes - i.e. with:
  - Basal
  - Basal bolus
  - Biphasic

Sen Gupta et al.Diabetes 2014; 63 (Suppl. 1): 1023-P

Association of British Clinical Diabetologists

Effectiveness in South Asians



Sandwell and West Birmingham Hospitals NHS
NHS Trust

The efficacy of exenatide and liraglutide among South Asians in the Association of British Clinical Diabetologists nationwide audits

KY Thong,[1] P Sen Gupta,[1,2] REJ Ryder[1]

[1]Department of Diabetes, City Hospital, Birmingham, UK; [2]Diabetes Research Group, King's College, London, UK.

Introduction

- GLP-1 receptor agonists (GLP-1RAs), including exenatide and liraglutide, have been shown to effectively lower HbA_{1c} and mean weight, with a low risk of hypoglycaemia, in patients with type 2 diabetes (T2D).[1]
- The nationwide liraglutide and exenatide audits are part of an initiative launched by the UK's Association of British Clinical Diabetologists (ABCD) to evaluate the real clinical use, efficacy and adverse effects of these agents.
- As part of these audits, anonymised data from patients with T2D treated with exenatide (n=6717 from 315 contributors, 126 centres, 2007–2009) or liraglutide (n=5551, 303 contributors, 106 centres, 2009–2012) were collected.
- We investigated whether exenatide and liraglutide are as effective among South Asian patients with T2D as among Caucasian patients.

Methods

- Data were obtained from two audit databases on the use of exenatide 10 µg twice daily and liraglutide 1.2 mg once daily in clinical practice. Patients switching from a thiazolidinedione, dipeptidyl peptidase-4 inhibitor or exenatide to liraglutide were excluded from analyses. After exclusions, this analysis examined 2561 exenatide-treated patients and 1526 liraglutide-treated patients.
- Latest data on HbA_{1c} and weight reduction at 32 weeks were compared between South Asian (Indian, Pakistani, Bangladeshi) and Caucasian patients, stratified by background non-insulin or insulin treatment.
- Analysis of covariance (ANCOVA) on HbA_{1c} and weight reduction was performed adjusting for baseline HbA_{1c}, body mass index (BMI) or weight, gender, age, duration of diabetes, number of oral antidiabetes drugs, total daily insulin dose and insulin dose changes as appropriate.

Results

Patients

- 134/2561 (5.2%) of patients treated with exenatide and 101/1526 (6.6%) of patients treated with liraglutide during the time periods examined were identified as non-mixed South Asian and with available HbA_{1c} data.
- Of these, 71/134 (exenatide) and 47/101 (liraglutide) were also being treated with insulin.
- Patient demographics and baseline data are shown in Table 1. South Asian patients had significantly lower mean baseline BMIs compared with Caucasian patients (exenatide 35.3 vs. 39.7 kg/m², p<0.001; liraglutide 37.1 vs. 39.6 kg/m², p=0.001).

Table 1. Patient demographics.

	Exenatide			Liraglutide		
	Caucasian	South Asian	*p*-value	Caucasian	South Asian	*p*-value
Age (years)	55.3±10.5	51.4±9.6	<0.001	55.8±10.7	49.5±11.1	<0.001
Duration of diabetes (years)	9 [5–13]	10 [7–15]	0.003	9 [6–13]	10 [7–16]	0.037
HbA_{1c} (%)	9.55±1.64	9.72±1.61	0.24	9.41±1.68	9.19±1.63	0.189
BMI (kg/m²)	39.7±8.2	35.3±7.4	<0.001	39.6±7.1	37.1±6.8	0.001

- An analysis of response based on concurrent treatment with insulin found a smaller mean change in HbA_{1c} in non-insulin-treated South Asian patients compared with non-insulin-treated Caucasian patients for both exenatide (−0.60% vs. −1.09%, p=0.08) and liraglutide (−0.85% vs. −1.31%, p=0.04) (Figure 1). No difference was seen among insulin-treated South Asian patients compared with Caucasian patients.

Figure 1. Change in HbA_{1c}, by insulin use.

Adjusted for diabetes treatment, baseline HbA_{1c}, BMI, age, gender and diabetes duration; SA, South Asian; C, Caucasian

Weight

- Prior to adjusting for lower baseline weight, South Asian patients overall showed significantly lower mean weight loss from exenatide (−5.0 kg vs. −3.5 kg, p=0.006) or liraglutide (−3.6 kg vs. −2.4 kg, p=0.033) when compared with Caucasian patients. This difference disappeared when adjusted for diabetes treatment, baseline weight, age, gender and diabetes duration.
- When analysed according to presence of concurrent insulin treatment, there were no differences in weight response seen between South Asians and Caucasians for either exenatide or liraglutide treatment (Figure 2).

Figure 2. Change in weight, by insulin use.

- GLP1-RAs may be less effective at improving glycaemic control amongst non-insulin treated South Asians

Thong et al. Abstract Book, 22nd World Diabetes Congress, IDF, Melbourne, Australia, 2-6 December 2013

ABCD
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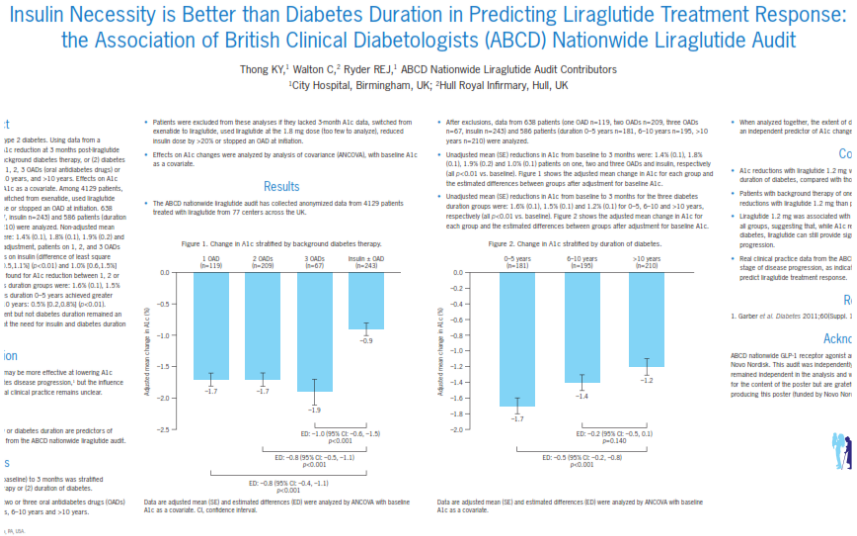
Liraglutide – predicting treatment response



Insulin Necessity is Better than Diabetes Duration in Predicting Liraglutide Treatment Response: the Association of British Clinical Diabetologists (ABCD) Nationwide Liraglutide Audit

Thong KY,[1] Walton C,[2] Ryder REJ,[1] ABCD Nationwide Liraglutide Audit Contributors

[1]City Hospital, Birmingham, UK; [2]Hull Royal Infirmary, Hull, UK

Results

Figure 1. Change in A1c stratified by background diabetes therapy.

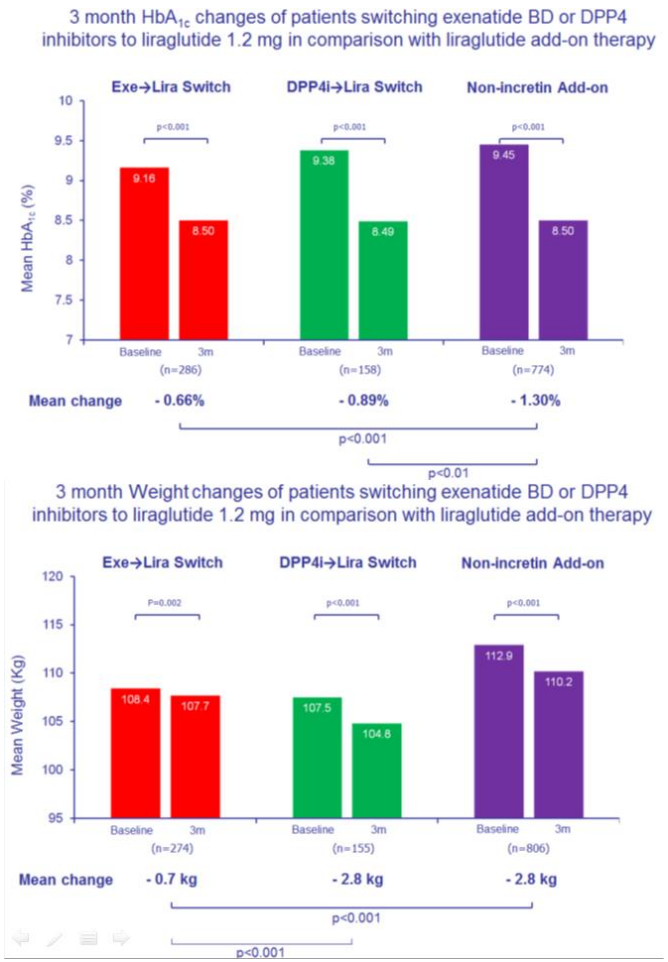
Figure 2. Change in A1c stratified by duration of diabetes.

- Long duration of diabetes and insulin use both predict reduced response with insulin use being the strongest predictor

Thong et al. Diabetes 2012; 61 (Suppl. 1): 1038P

Association of British Clinical Diabetologists

Switching to liraglutide from BD exenatide or from DPP4 inhibitor



- Improvements in HbA1c and weight are seen when switching from exenatide and DPP4 inhibitors to liraglutide

Ryder and Gough. Presentation at IDF Scientific Update Satellite Meeting, Dubai, December 6 2011
http://www.diabetologists-abcd.org.uk/liraglutide_audit/Shared%20Documents/IDF_Dubai2011_SUM.pdf

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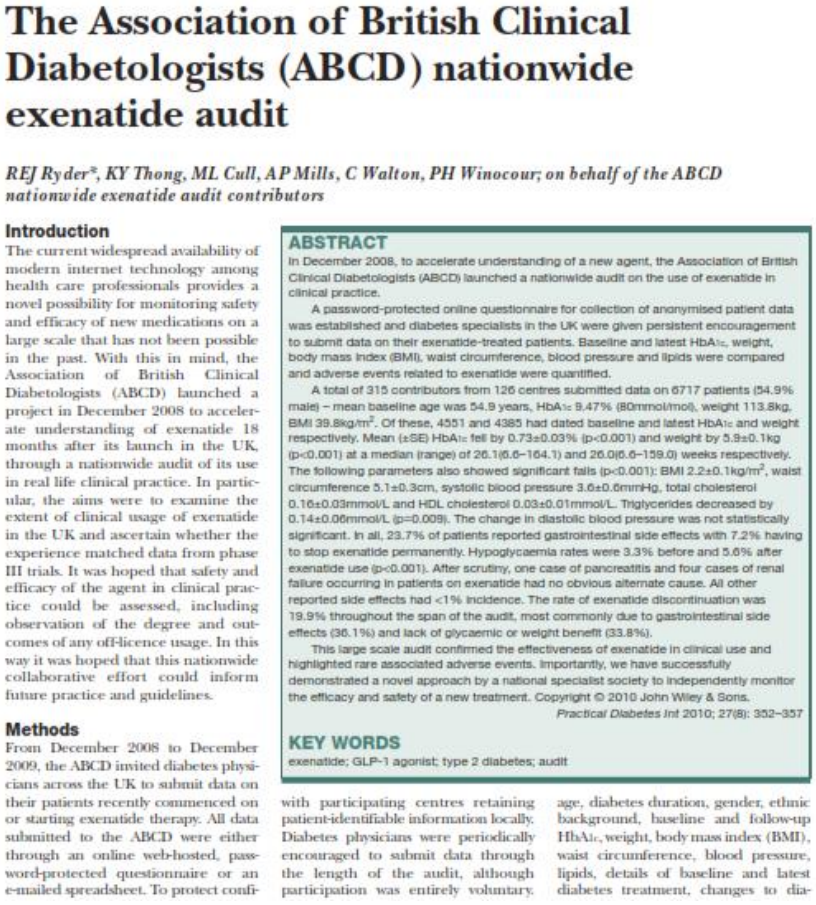
Safety



The Association of British Clinical Diabetologists (ABCD) nationwide exenatide audit

REJ Ryder, KY Thong, ML Cull, AP Mills, C Walton, PH Winocour; on behalf of the ABCD nationwide exenatide audit contributors*

ABSTRACT

In December 2008, to accelerate understanding of a new agent, the Association of British Clinical Diabetologists (ABCD) launched a nationwide audit on the use of exenatide in clinical practice.

A password-protected online questionnaire for collection of anonymised patient data was established and diabetes specialists in the UK were given persistent encouragement to submit data on their exenatide-treated patients. Baseline and latest HbA_{1c}, weight, body mass index (BMI), waist circumference, blood pressure and lipids were compared and adverse events related to exenatide were quantified.

A total of 315 contributors from 126 centres submitted data on 6717 patients (54.9% male) – mean baseline age was 54.9 years, HbA_{1c} 9.47% (80mmol/mol), weight 113.8kg, BMI 39.8kg/m^2. Of these, 4551 and 4385 had dated baseline and latest HbA_{1c} and weight respectively. Mean (±SE) HbA_{1c} fell by 0.73±0.03% ($p<0.001$) and weight by 5.9±0.1kg ($p<0.001$) at a median (range) of 26.1(6.6–164.1) and 26.0(6.6–159.0) weeks respectively. The following parameters also showed significant falls ($p<0.001$): BMI 2.2±0.1kg/m^2, waist circumference 5.1±0.3cm, systolic blood pressure 3.6±0.6mmHg, total cholesterol 0.16±0.03mmol/L and HDL cholesterol 0.03±0.01mmol/L. Triglycerides decreased by 0.14±0.06mmol/L ($p=0.009$). The change in diastolic blood pressure was not statistically significant. In all, 23.7% of patients reported gastrointestinal side effects with 7.2% having to stop exenatide permanently. Hypoglycaemia rates were 3.3% before and 5.6% after exenatide use ($p<0.001$). After scrutiny, one case of pancreatitis and four cases of renal failure occurring in patients on exenatide had no obvious alternate cause. All other reported side effects had <1% incidence. The rate of exenatide discontinuation was 19.9% throughout the span of the audit, most commonly due to gastrointestinal side effects (36.1%) and lack of glycaemic or weight benefit (33.8%).

This large scale audit confirmed the effectiveness of exenatide in clinical use and highlighted rare associated adverse events. Importantly, we have successfully demonstrated a novel approach by a national specialist society to independently monitor the efficacy and safety of a new treatment.

Practical Diabetes Int 2010; 27(8): 352–357

KEY WORDS

exenatide; GLP-1 agonist; type 2 diabetes; audit

Introduction

The current widespread availability of modern internet technology among health care professionals provides a novel possibility for monitoring safety and efficacy of new medications on a large scale that has not been possible in the past. With this in mind, the Association of British Clinical Diabetologists (ABCD) launched a project in December 2008 to accelerate understanding of exenatide 18 months after its launch in the UK, through a nationwide audit of its use in real life clinical practice. In particular, the aims were to examine the extent of clinical usage of exenatide in the UK and ascertain whether the experience matched data from phase III trials. It was hoped that safety and efficacy of the agent in clinical practice could be assessed, including observation of the degree and outcomes of any off-licence usage. In this way it was hoped that this nationwide collaborative effort could inform future practice and guidelines.

Methods

From December 2008 to December 2009, the ABCD invited diabetes physicians across the UK to submit data on their patients recently commenced on or starting exenatide therapy. All data submitted to the ABCD were either through an online web-hosted, password-protected questionnaire or an e-mailed spreadsheet. To protect confi- with participating centres retaining patient-identifiable information locally. Diabetes physicians were periodically encouraged to submit data through the length of the audit, although participation was entirely voluntary. age, diabetes duration, gender, ethnic background, baseline and follow-up HbA_{1c}, weight, body mass index (BMI), waist circumference, blood pressure, lipids, details of baseline and latest diabetes treatment, changes to dia-

- In some patients the nausea, vomiting or diarrhoea was so severe that they developed transient acute kidney injury
- There have been no other new safety issues uncovered

Ryder et al. Practical Diabetes International 2010; 27(8): 352-357

Association of British Clinical Diabetologists

Advert

- I hope you agree we have learned a lot form these audits
- *All of you* please join the current ABCD audits!

Please join the current ABCD audits on N3

- Dapagliflozin
- Exenatide QW

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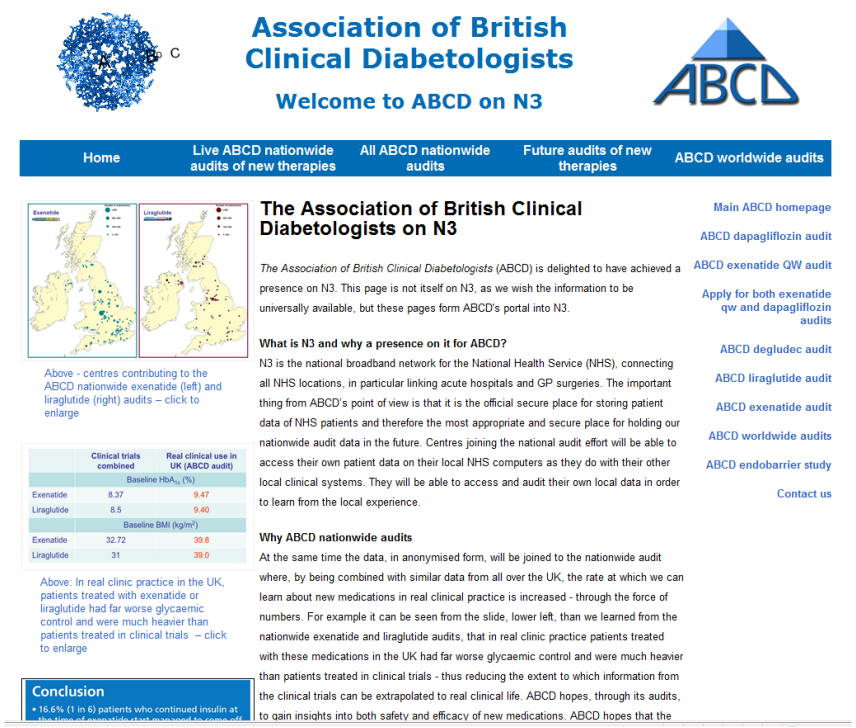
What is N3 and why a presence for ABCD?



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Welcome to ABCD on N3

ABCD

Home | Live ABCD nationwide audits of new therapies | All ABCD nationwide audits | Future audits of new therapies | ABCD worldwide audits

Above - centres contributing to the ABCD nationwide exenatide (left) and liraglutide (right) audits – click to enlarge

	Clinical trials combined	Real clinical use in UK (ABCD audit)
Baseline HbA_{1c} (%)		
Exenatide	8.37	9.47
Liraglutide	8.5	9.40
Baseline BMI (kg/m^2)		
Exenatide	32.72	39.8
Liraglutide	31	39.0

Above: In real clinic practice in the UK, patients treated with exenatide or liraglutide had far worse glycaemic control and were much heavier than patients treated in clinical trials – click to enlarge

Conclusion

• 16.6% (1 in 6) patients who continued insulin at

The Association of British Clinical Diabetologists on N3

The Association of British Clinical Diabetologists (ABCD) is delighted to have achieved a presence on N3. This page is not itself on N3, as we wish the information to be universally available, but these pages form ABCD's portal into N3.

What is N3 and why a presence on it for ABCD?

N3 is the national broadband network for the National Health Service (NHS), connecting all NHS locations, in particular linking acute hospitals and GP surgeries. The important thing from ABCD's point of view is that it is the official secure place for storing patient data of NHS patients and therefore the most appropriate and secure place for holding our nationwide audit data in the future. Centres joining the national audit effort will be able to access their own patient data on their local NHS computers as they do with their other local clinical systems. They will be able to access and audit their own local data in order to learn from the local experience.

Why ABCD nationwide audits

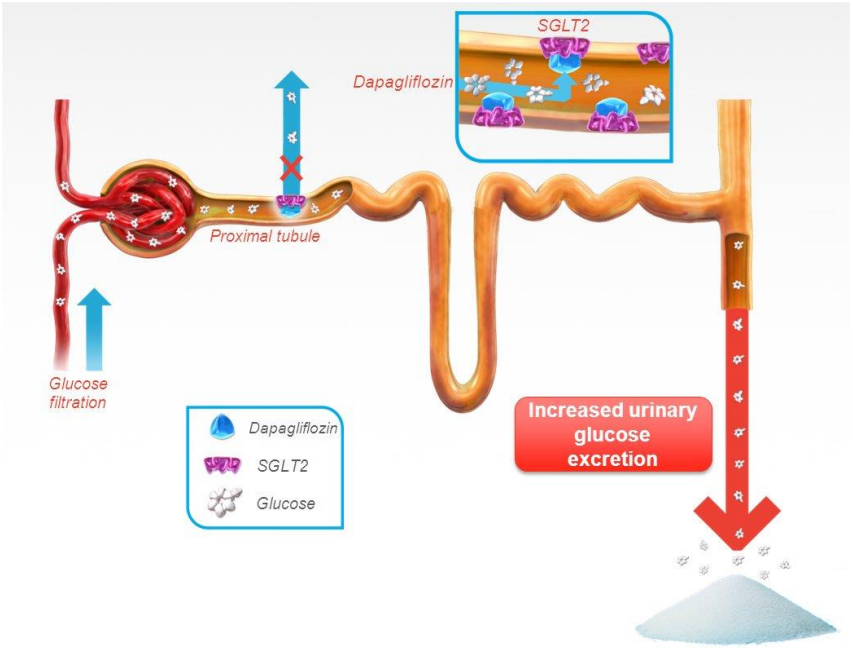
At the same time the data, in anonymised form, will be joined to the nationwide audit where, by being combined with similar data from all over the UK, the rate at which we can learn about new medications in real clinical practice is increased - through the force of numbers. For example it can be seen from the slide, lower left, than we learned from the nationwide exenatide and liraglutide audits, that in real clinic practice patients treated with these medications in the UK had far worse glycaemic control and were much heavier than patients treated in clinical trials - thus reducing the extent to which information from the clinical trials can be extrapolated to real clinical life. ABCD hopes, through its audits, to gain insights into both safety and efficacy of new medications. ABCD hopes that the

Main ABCD homepage
ABCD dapagliflozin audit
ABCD exenatide QW audit
Apply for both exenatide qw and dapagliflozin audits
ABCD degludec audit
ABCD liraglutide audit
ABCD exenatide audit
ABCD worldwide audits
ABCD endobarrier study
Contact us

- N3 is the national broadband network for the NHS, connecting all NHS locations
- The important thing from ABCD's point of view is that it is the official secure place for storing patient data of NHS patients and therefore the most appropriate and secure place for holding our nationwide audit data in the future

http://www.diabetologists-abcd.org.uk/n3/n3.htm

SLGT2 inhibitors – a chance to learn in the same way about a new class

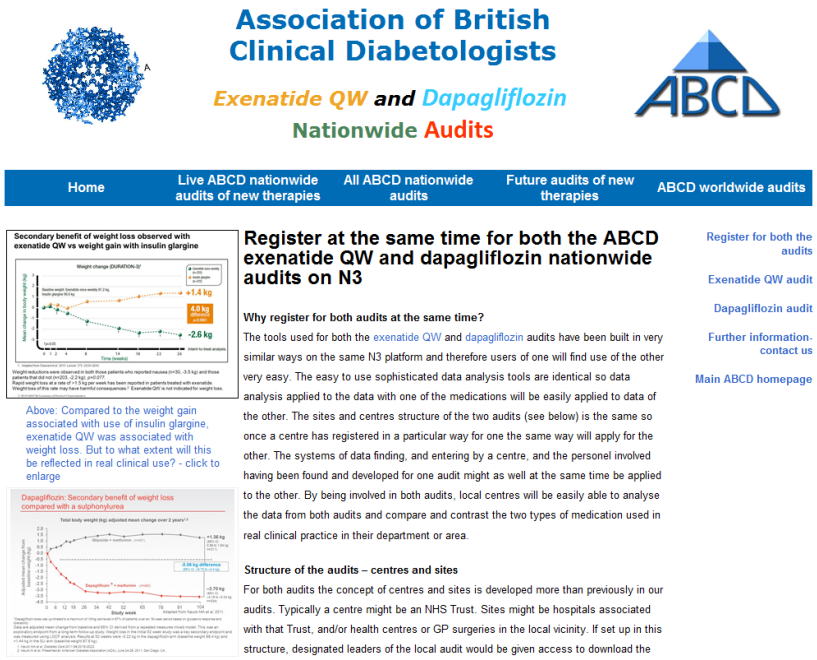


- Dapagliflozin
- Exenatide QW

Association of British Clinical Diabetologists

http://www.diabetologists-abcd.org.uk/n3/Dapagliflozin_Audit.htm

Audit tools are very similar – consider doing both at the same time?



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Exenatide QW ***and*** *Dapagliflozin*

Nationwide Audits

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Secondary benefit of weight loss observed with exenatide QW vs weight gain with insulin glargine

Above: Compared to the weight gain associated with use of insulin glargine, exenatide QW was associated with weight loss. But to what extent will this be reflected in real clinical use? - click to enlarge

Dapagliflozin: Secondary benefit of weight loss compared with a sulphonylurea

Register at the same time for both the ABCD exenatide QW and dapagliflozin nationwide audits on N3

Register for both the audits

Exenatide QW audit

Dapagliflozin audit

Further information- contact us

Main ABCD homepage

Why register for both audits at the same time?

The tools used for both the exenatide QW and dapagliflozin audits have been built in very similar ways on the same N3 platform and therefore users of one will find use of the other very easy. The easy to use sophisticated data analysis tools are identical so data analysis applied to the data with one of the medications will be easily applied to data of the other. The sites and centres structure of the two audits (see below) is the same so once a centre has registered in a particular way for one the same way will apply for the other. The systems of data finding, and entering by a centre, and the personel involved having been found and developed for one audit might as well at the same time be applied to the other. By being involved in both audits, local centres will be easily able to analyse the data from both audits and compare and contrast the two types of medication used in real clinical practice in their department or area.

Structure of the audits – centres and sites

For both audits the concept of centres and sites is developed more than previously in our audits. Typically a centre might be an NHS Trust. Sites might be hospitals associated with that Trust, and/or health centres or GP surgeries in the local vicinity. If set up in this structure, designated leaders of the local audit would be given access to download the

- Dapagliflozin
- Exenatide QW

http://www.diabetologists-abcd.org.uk/n3/n3_Audits_Register_Both.htm

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Please join the current ABCD audits

- The current tools have "sophisticated output"
- Makes it very easy for you (or your SpR, or DSN, or medical student …) to analyse your local data

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Dapagliflozin
Nationwide Audit

ABCD
Association of British Clinical Diabetologists

Home | Users | Centres | Sites | Export Data | Edit profile | Logout

Export Data

○ Basic Output ◉ Sophisticated Output

Export on a [3] monthly basis. (Leave blank not to group)

Check All Uncheck All

Dapagliflozin Followup Questionnaire [Check All] [Uncheck All]

Surgery [Check All] [Uncheck All]

Has this patient had bariatric surgery?
☐ Yes ☐ No

Current Medical Status [Check All] [Uncheck All]

Patient still taking dapagliflozin? [Check All] [Uncheck All]
☐ Yes ☐ Temporarily stopped, to restart ☐ Permanently stopped

Test Results [Check All] [Uncheck All]

Date of Visit
☐ Date of Visit

Blood Pressure [Check All] [Uncheck All]
☐ SBP ☐ DBP ☐ Date of Measure

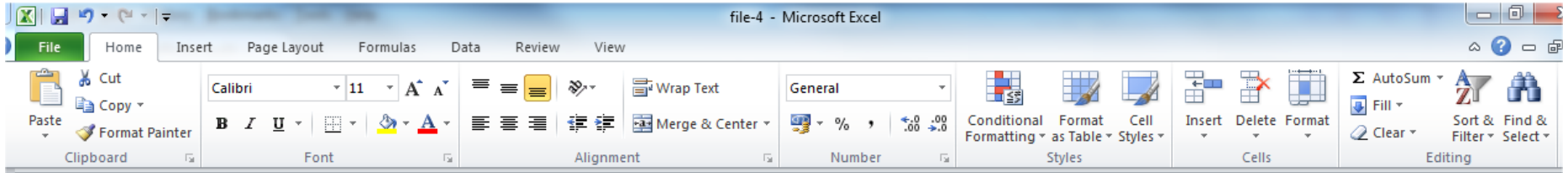
Current Weight [Check All] [Uncheck All]
☑ Weight ☐ Date of Measure ☐ BMI

Were the following blood tests taken on the same day as each other
☐ Yes ☐ No

HbA1c [Check All] [Uncheck All]
☑ percentage value ☐ or mmol/mol ☐ Date of Measure

Lipids [Check All] [Uncheck All]
☐ Triglyceride Value ☐ HDL Value ☐ Total Cholesterol ☐ Date of Measures

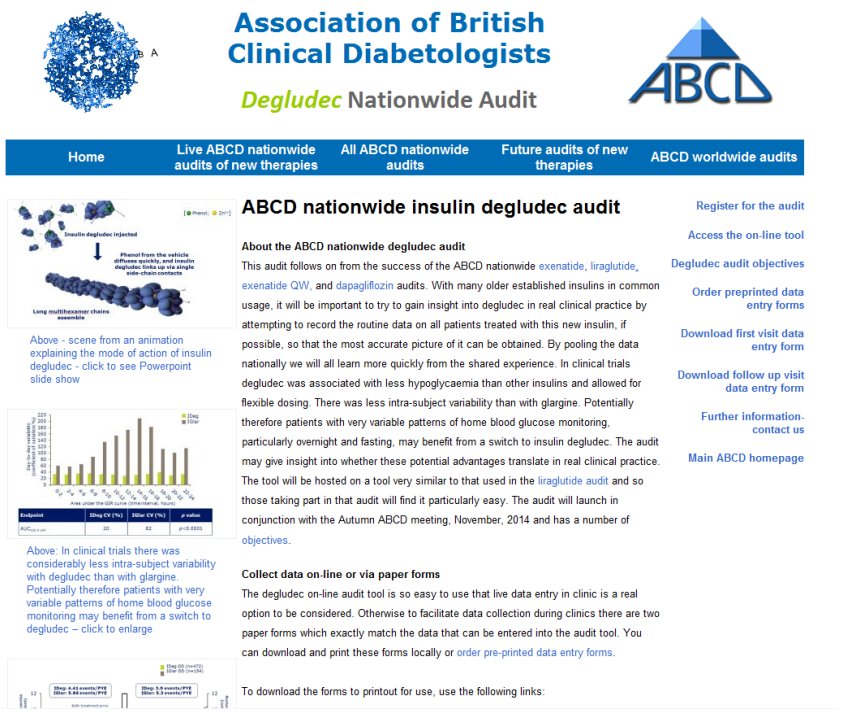
Alanine Aminotransferase - ALT



O1 | Initiation Date

	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB	AC
1	Initiation Date	Weight (Xkg)							HbA1c percentage value (X%)						
2		Baseline Visit Date	0 months	3 months	6 months	9 months	12 months	15 months	Baseline Visit Date	0 months	3 months	6 months	9 months	12 months	15 months
3	01/07/2014	01/07/2014	76						01/07/2014	8.7					
4	25/03/2013	05/02/2013	102.9		95.7				05/02/2013	10.7		7.5			
5	22/04/2013	05/02/2013	96.5	95					05/02/2013	10	8.6				
6	30/04/2013	06/03/2013	108.4				108.9		06/03/2013	9.7				9.9	
7	25/04/2013	03/04/2013	115	115			106.3		03/04/2013	10.9	9			8.5	
8	09/04/2013	09/04/2013	129.8						09/04/2013	8.3					
9	07/08/2013	18/08/2013	122.9	119		122.8	119		18/08/2013	11.3	9.1		10.8	10.3	
10	01/05/2013	08/05/2013	94	89.3					08/05/2013	8.2	8.6				
11	15/08/2014	15/08/2014	92.7						15/08/2014	8.3					
12	15/07/2014	15/07/2014	116						15/07/2014	8.2					
13	12/08/2014	12/08/2014	80.1						12/08/2014	9.7					
14	27/06/2014	26/06/2014	103.4	98.6					26/06/2014	8.3	7.1				
15	24/06/2014	24/03/2014	114						24/03/2014	11.8					
16	20/06/2014	20/06/2014	75.2						20/06/2014	10.5					
17	20/06/2014	20/06/2014	103.6						20/06/2014	7.9					
18	27/05/2014	27/05/2014	82						27/05/2014	7.9					
19	29/10/2013	29/10/2013	114.3						29/10/2013	10.3					
20	29/07/2014	15/05/2014	100						15/05/2014	9.7					
21	22/01/2014	22/01/2014	112						22/01/2014	8.4					
22	10/03/2014	10/03/2014	98	94.3	91				10/03/2014	11.2	12.1	11.6			
23	24/06/2014	24/06/2014	116	114.7					24/06/2014	10	9.5				
24	01/01/2014	01/01/2014	70						01/01/2014	8.6					
25	10/01/2014	10/01/2014	75						10/01/2014	9.5					
26	28/01/2014	28/01/2014	90						28/01/2014	9.5					
27	04/07/2014	30/06/2014	94.4	91					30/06/2014	8.3	9.8				
28	28/10/2013	18/11/2013	114		109	109			18/11/2013	11.7		9.8	9.8		
29	01/07/2014	01/07/2014	166						01/07/2014	10.9					
30	08/10/2013	08/10/2013	117	115	120	119			08/10/2013	13.1	11.3	11.1	11.4		
31	27/03/2014	27/03/2014	92						27/03/2014	8.6					
32	20/05/2014	14/08/2014	82						14/08/2014	7.5					
33	15/05/2014	15/05/2014	99.6						15/05/2014	10.5					
34	11/06/2014	11/06/2014	97.9	97.5					11/06/2014	10.5	8.6				
35	06/02/2014	06/02/2014	84.5						06/02/2014	10.4					
36	21/08/2014	21/08/2014	97.8						21/08/2014	11.7					
37	13/11/2013	13/11/2013	95.6		87.5				13/11/2013	8.4		9.7			
38	07/05/2014	07/05/2014	106.5						07/05/2014	11.1					
39	18/07/2014	18/07/2014	112						18/07/2014	8					
40	09/07/2014	09/07/2014	138.8						09/07/2014	9.5					

Today - November 7, 2014
Launch of the ABCD nationwide degludec audit



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Degludec Nationwide Audit

ABCD

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Above - scene from an animation explaining the mode of action of insulin degludec - click to see Powerpoint slide show

Above: In clinical trials there was considerably less intra-subject variability with degludec than with glargine. Potentially therefore patients with very variable patterns of home blood glucose monitoring may benefit from a switch to degludec – click to enlarge

ABCD nationwide insulin degludec audit

About the ABCD nationwide degludec audit

This audit follows on from the success of the ABCD nationwide exenatide, liraglutide, exenatide QW, and dapagliflozin audits. With many older established insulins in common usage, it will be important to try to gain insight into degludec in real clinical practice by attempting to record the routine data on all patients treated with this new insulin, if possible, so that the most accurate picture of it can be obtained. By pooling the data nationally we will all learn more quickly from the shared experience. In clinical trials degludec was associated with less hypoglycaemia than other insulins and allowed for flexible dosing. There was less intra-subject variability than with glargine. Potentially therefore patients with very variable patterns of home blood glucose monitoring, particularly overnight and fasting, may benefit from a switch to insulin degludec. The audit may give insight into whether these potential advantages translate in real clinical practice. The tool will be hosted on a tool very similar to that used in the liraglutide audit and so those taking part in that audit will find it particularly easy. The audit will launch in conjunction with the Autumn ABCD meeting, November, 2014 and has a number of objectives.

Collect data on-line or via paper forms

The degludec on-line audit tool is so easy to use that live data entry in clinic is a real option to be considered. Otherwise to facilitate data collection during clinics there are two paper forms which exactly match the data that can be entered into the audit tool. You can download and print these forms locally or order pre-printed data entry forms.

To download the forms to printout for use, use the following links:

Register for the audit

Access the on-line tool

Degludec audit objectives

Order preprinted data entry forms

Download first visit data entry form

Download follow up visit data entry form

Further information- contact us

Main ABCD homepage

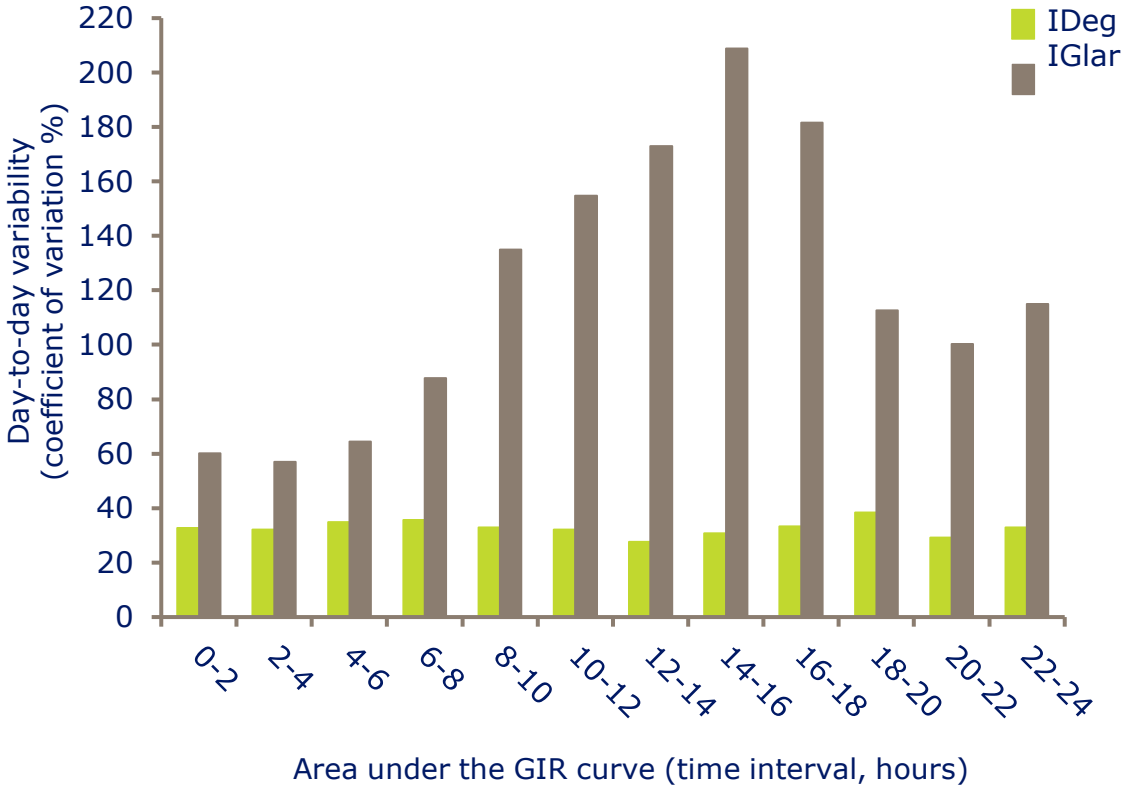
- Even if you have only a couple of patients
- If everyone contributes their couple of patients ….
- We must aim to get every degludec patient in the UK in the audit

ABCD

Association of British Clinical Diabetologists

http://www.diabetologists-abcd.org.uk/Degludec/Degludec_Audit.htm

Variability in glucose-lowering effect over 24 hours at steady state



Endpoint	IDeg CV (%)	IGlar CV (%)	*p* value
$AUC_{GIR,0\text{-}24h}$	20	82	$p<0.0001$

Heise *et al. Diabetes Obes Metab* 2012;14:859-64

ExenatideQW Worldwide Audit

Association of British Clinical Diabetologists

Login

Username

Password

Login

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The ABCD worldwide exenatide QW audit is an independent audit supported by an unrestricted grant from Astra Zeneca

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