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ABCD Nationwide Exenatide and Liraglutide Audits

Dr Bob Ryder and Professor Stephen Gough
on behalf of the ABCD nationwide exenatide and liraglutide audit contributors

Scientific Update Satellite Meeting - IDF Dubai
6 December 2011

Disclosures

- Design, conduct, analysis and reporting of audits independently performed by ABCD; funded by a grant from Eli Lilly for exenatide audit and Novo Nordisk for liraglutide audit; written agreements with companies governing these audits are ABPI compliant
- Dr Ryder:
  - During the last 5 years Dr Ryder has received educational sponsorship, speaker fees and consultancy fees from a number of pharmaceutical companies including Eli Lilly, GlaxoSmithKline, Novo Nordisk, sanofi-aventis and Takeda
- Professor Gough:
  - During the last 5 years Professor Gough has received research sponsorship and honoraria from Novo Nordisk, Eli Lilly, sanofi-aventis, and Takeda

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BACKGROUND:
REASONS FOR DOING AUDIT

THE ABCD NATIONWIDE GLP-1 AUDIT PROGRAMME

Why conduct an audit?

- To assess therapeutic efficacy in routine clinical practice in the UK
- To evaluate tolerability and safety profile in UK clinical practice

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Audit characteristics

	Exenatide	Liraglutide
Dates of data	2007-2009	2009-2011
Centres	126	77
Contributors	315	265
Patients	6717	4129
Duration of follow-up, median (range)	26 (0 – 159) weeks	26 (0 – 103) weeks

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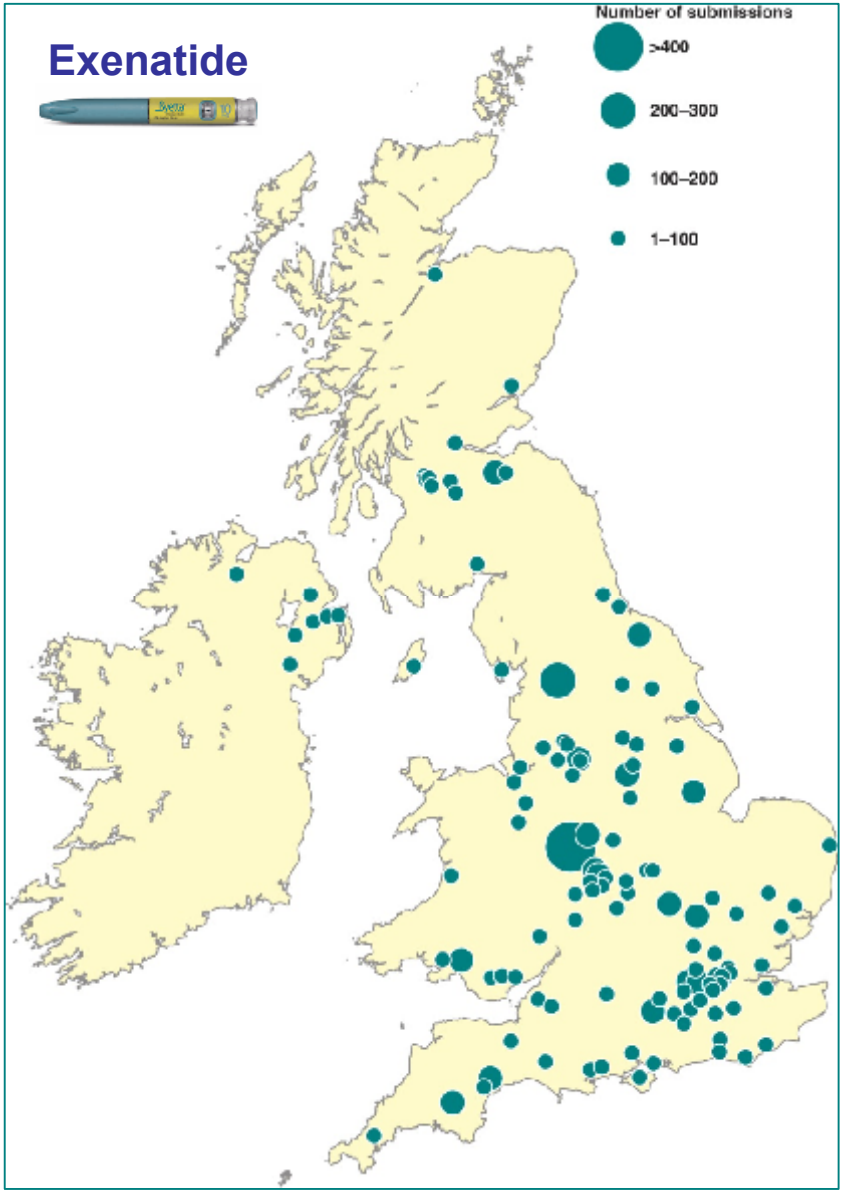
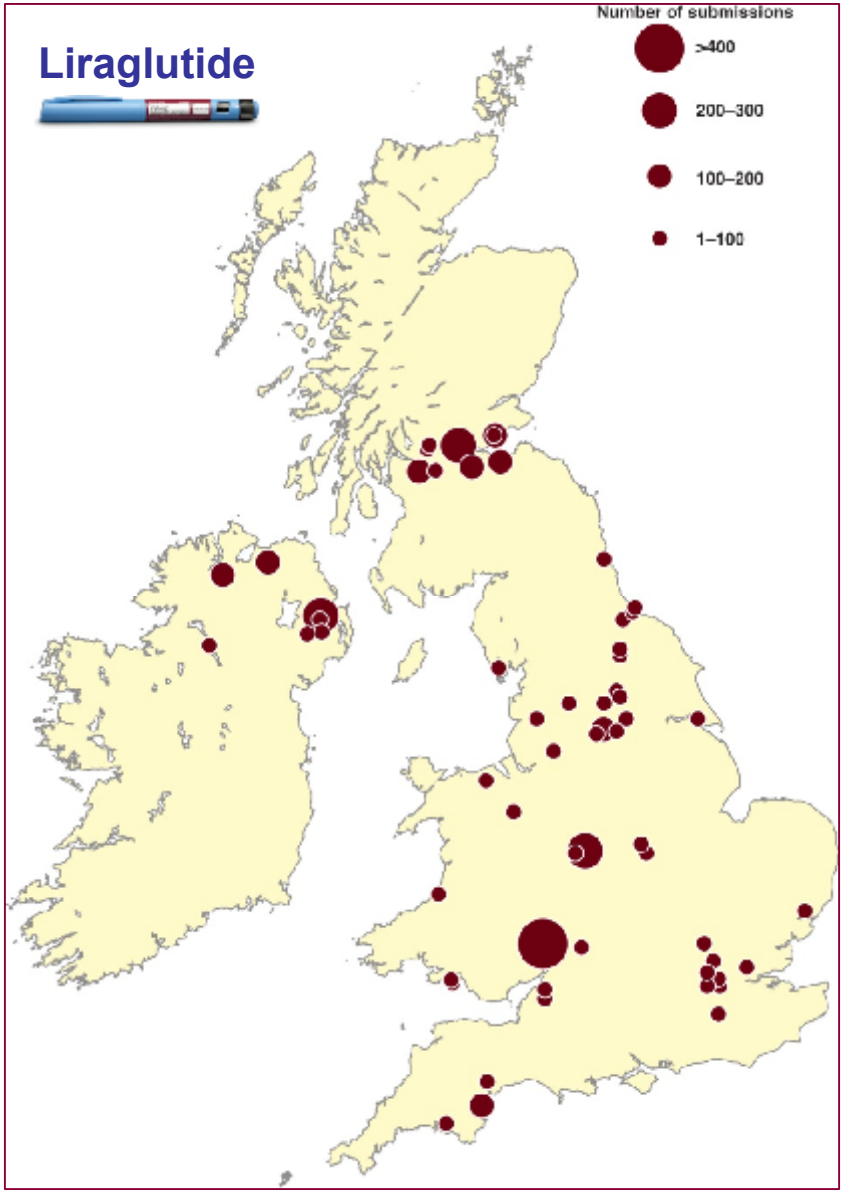
Nationwide contribution to exenatide and liraglutide national audit





Baseline characteristics

	Exenatide	Liraglutide
n	6717	3247 (from 4129)
Male (%)	54.9	54.6
Caucasian (%)	84.4	90.8
Age (yrs)	54.9 (10.6)	55.5 (11.1)
Diabetes duration (yrs)	8 (5-13)	9 (5-13)
HbA_{1c} (%)	9.47 (1.69)	9.40 (1.73)
Weight (kg)	113.8 (23.4)	110.9 (22.8)
BMI (kg/m^2)	39.8 (8.0)	39.0 (7.4)

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

Results for exenatide adapted from Ryder *et al. Pract Diab Int* 2010;27:352-357b

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Baseline characteristics – clinical trials versus real clinical use in UK

	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

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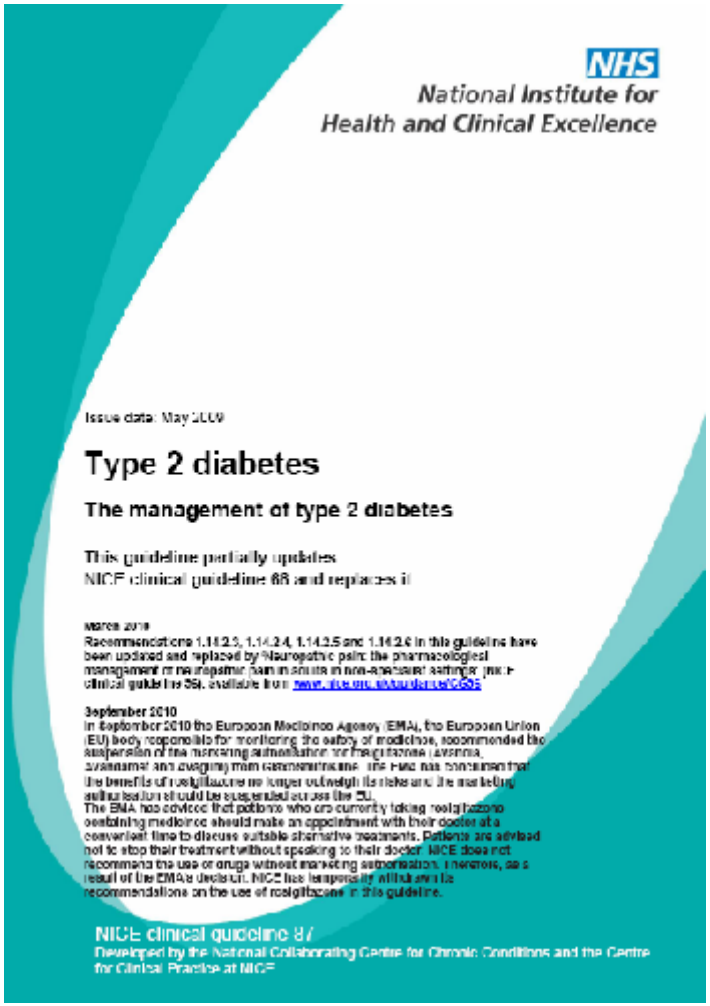
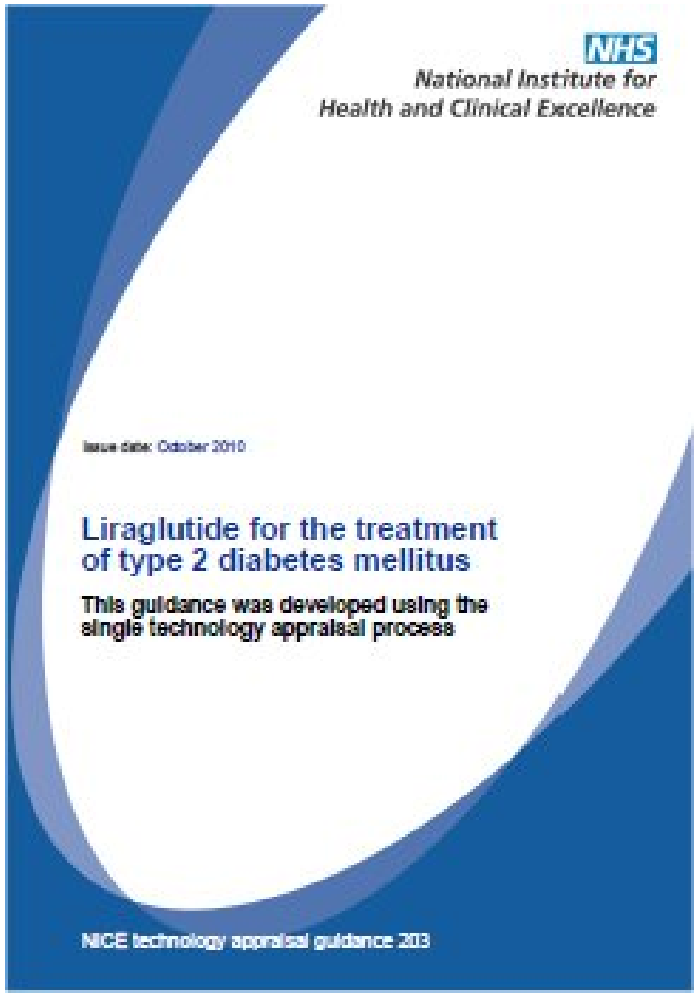
NICE guidelines for GLP1 receptor agonist use





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GLP-1 mimetic (exenatide)

1.1.14 Consider adding a GLP-1 mimetic (exenatide) as third-line therapy to first-line metformin and a second-line sulfonylurea when control of blood glucose remains or becomes inadequate (HbA$_{1c}$ ≥ 7.5% or other higher level agreed with the individual), and the person has:

- a body mass index (BMI) ≥ 35.0 kg/m^2 in those of European descent (with appropriate adjustment for other ethnic groups) and specific psychological or medical problems associated with high body weight, or
- a BMI < 35.0 kg/m^2, and therapy with insulin would have significant occupational implications or weight loss would benefit other significant obesity-related comorbidities.

1.1.15 Only continue GLP-1 mimetic (exenatide) therapy if the person has had a beneficial metabolic response (a reduction of at least 1.0 percentage point in HbA$_{1c}$ and a weight loss of at least 3% of initial body weight at 6 months).

1.1.16 Discuss the potential benefits and risks of treatment with a GLP-1 mimetic (exenatide) with the person to enable them to make an informed decision.

Insulin therapy

[3] At the time of publication pioglitazone was the only thiazolidinedione with UK marketing authorisation for use with insulin.

1.1 Liraglutide 1.2 mg daily in triple therapy regimens (in combination with metformin and a sulfonylurea, or metformin and a thiazolidinedione) is recommended as an option for the treatment of people with type 2 diabetes, only if used as described for exenatide in 'Type 2 diabetes: the management of type 2 diabetes' (NICE clinical guideline 87); that is, when control of blood glucose remains or becomes inadequate (HbA1c ≥ 7.5%, or other higher level agreed with the individual), and the person has:

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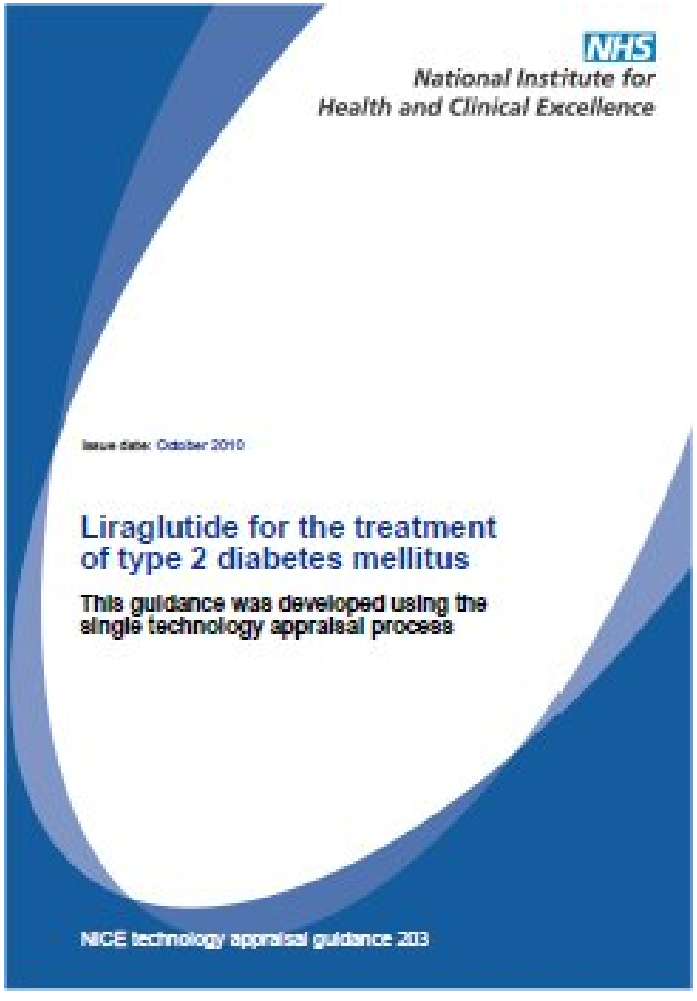
NICE only supports the 1.2 mg dose of liraglutide



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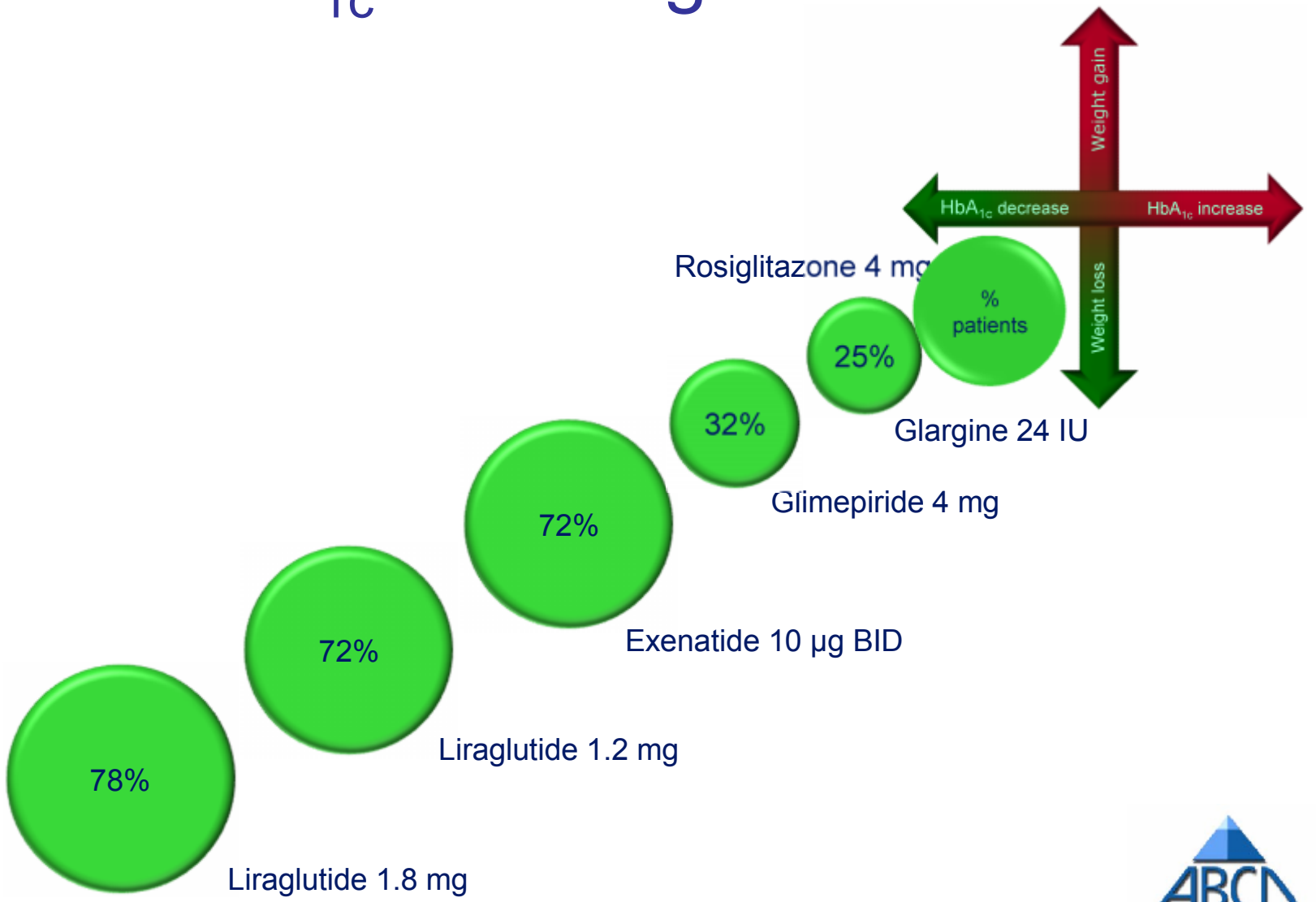
HbA_{1c} AND WEIGHT CHANGES

Percentage of subjects achieving fall in HbA_{1c} and weight loss



Data on file, Novo Nordisk

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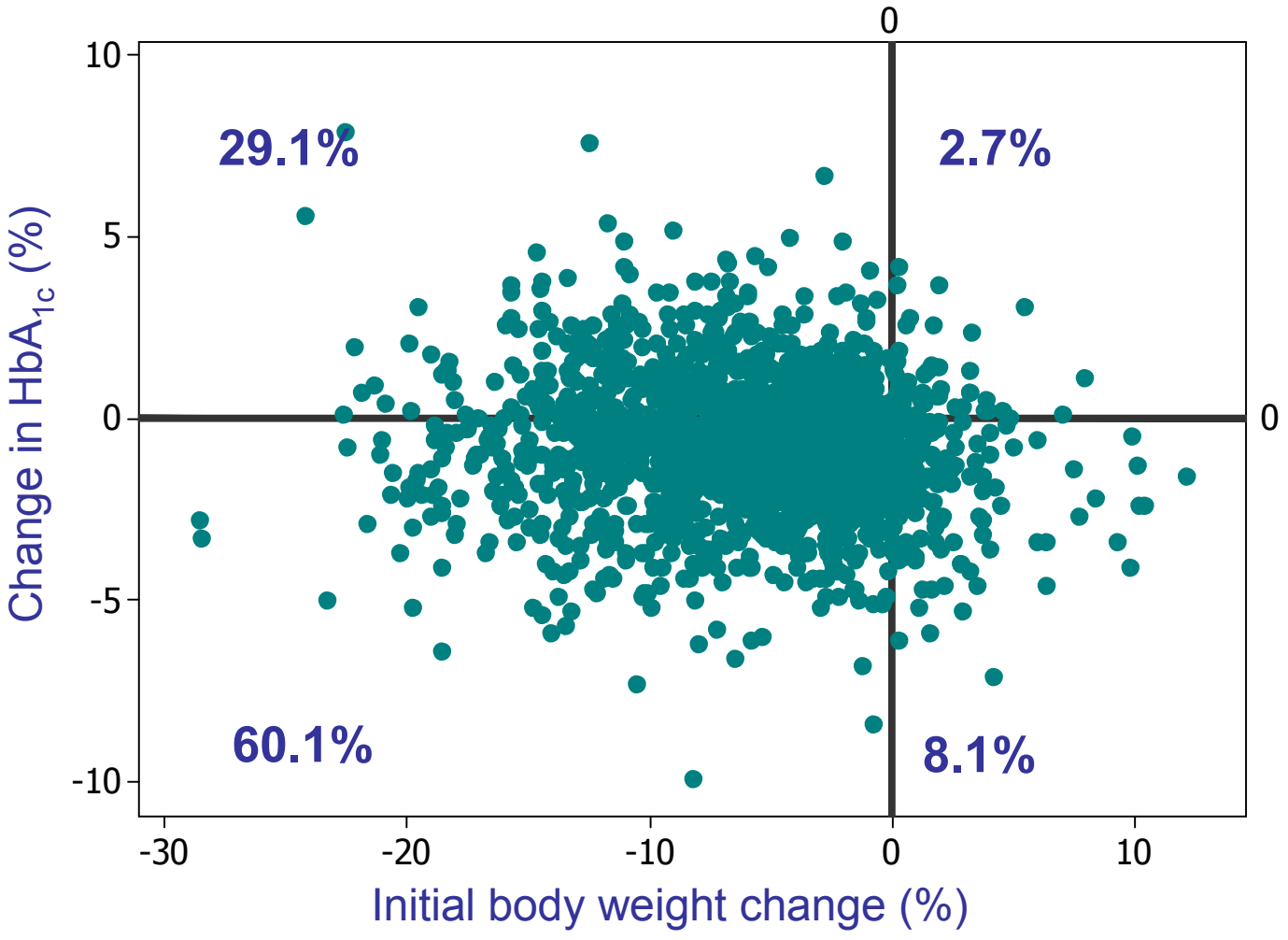
HbA_{1c} and weight changes at 6 months in 1882 patients on exenatide



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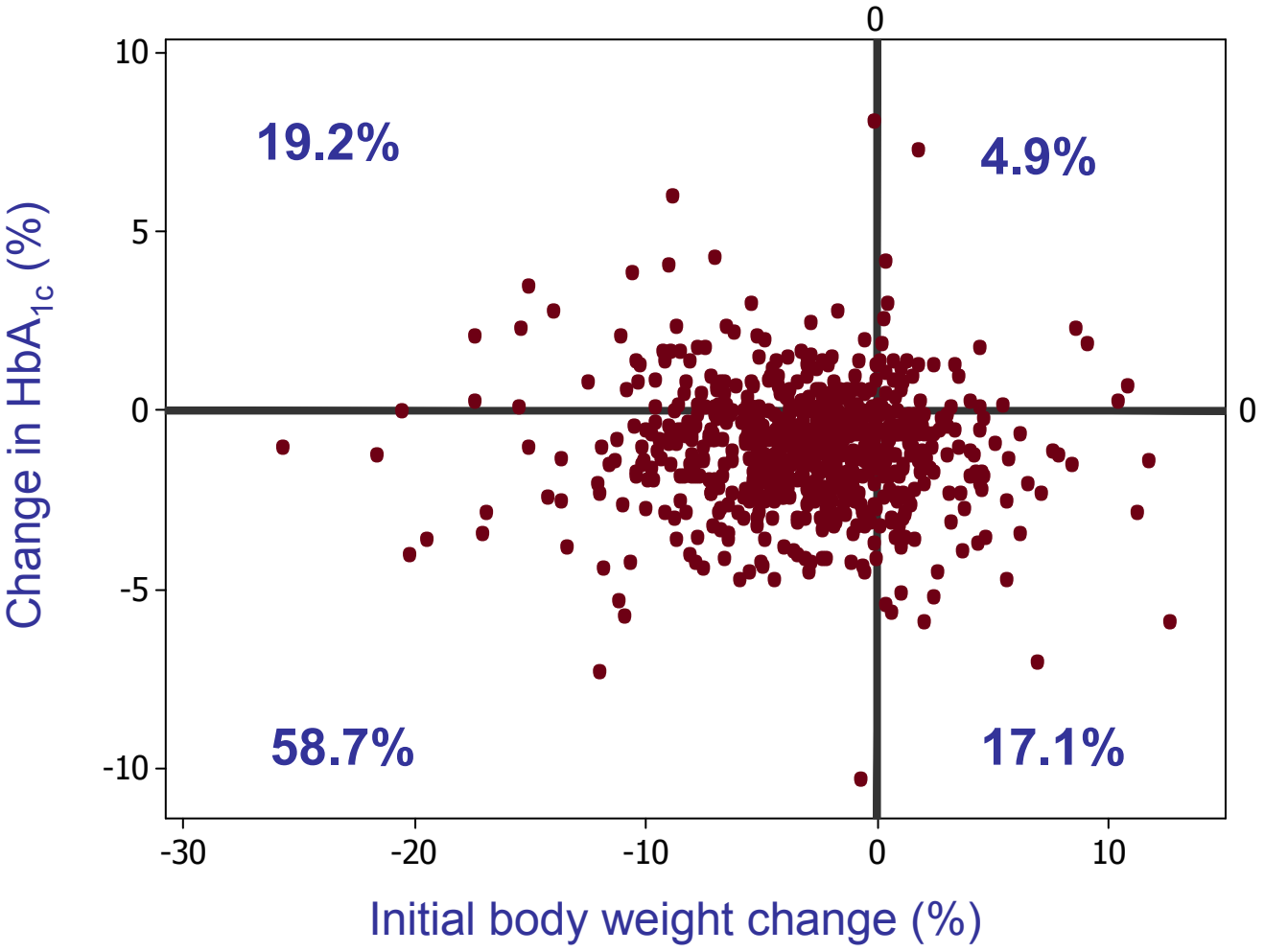
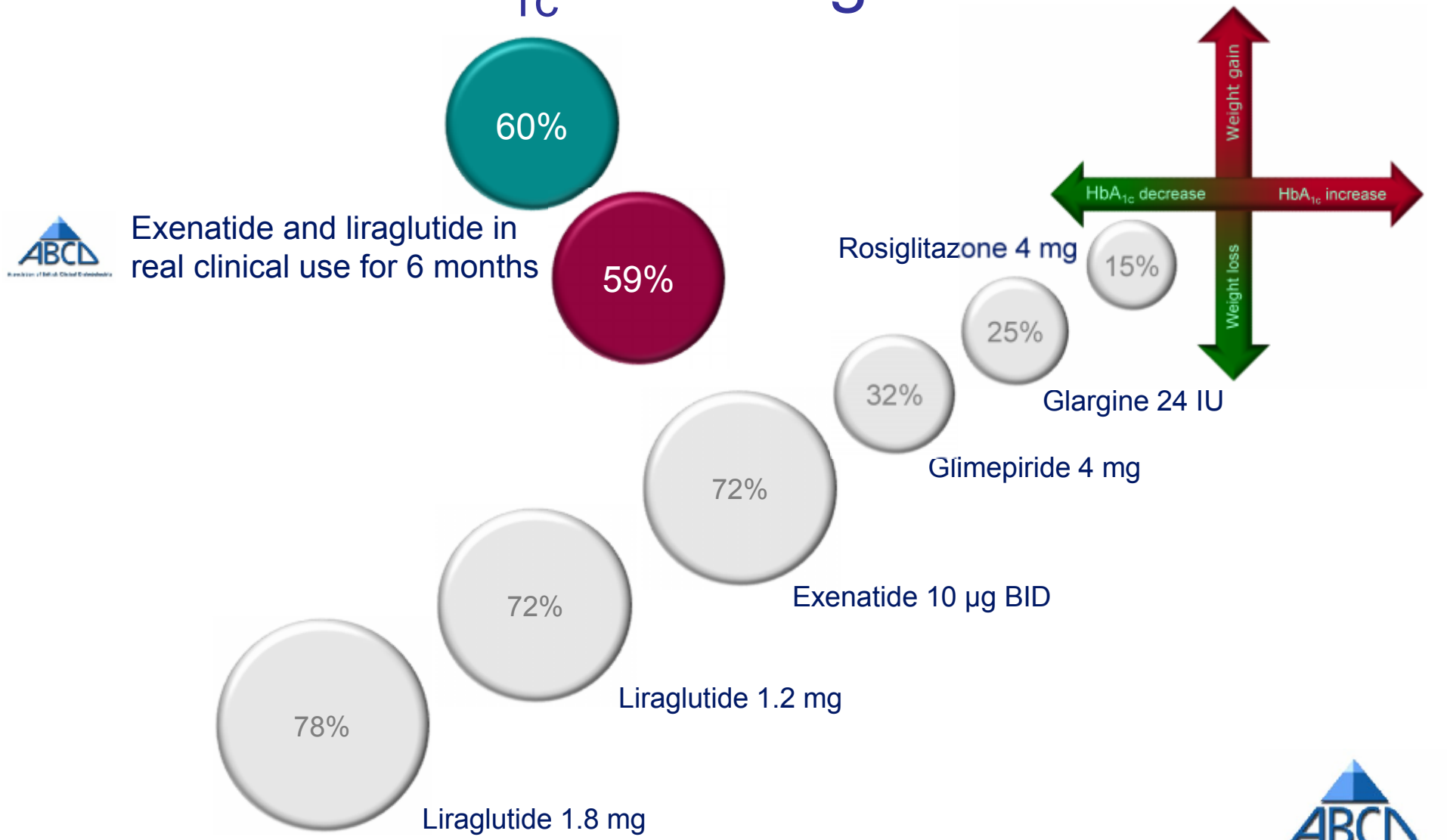
HbA_{1c} and weight changes at 6 months in 729 patients on liraglutide



Percentage of subjects achieving fall in HbA_{1c} and weight loss



Data on file, Novo Nordisk

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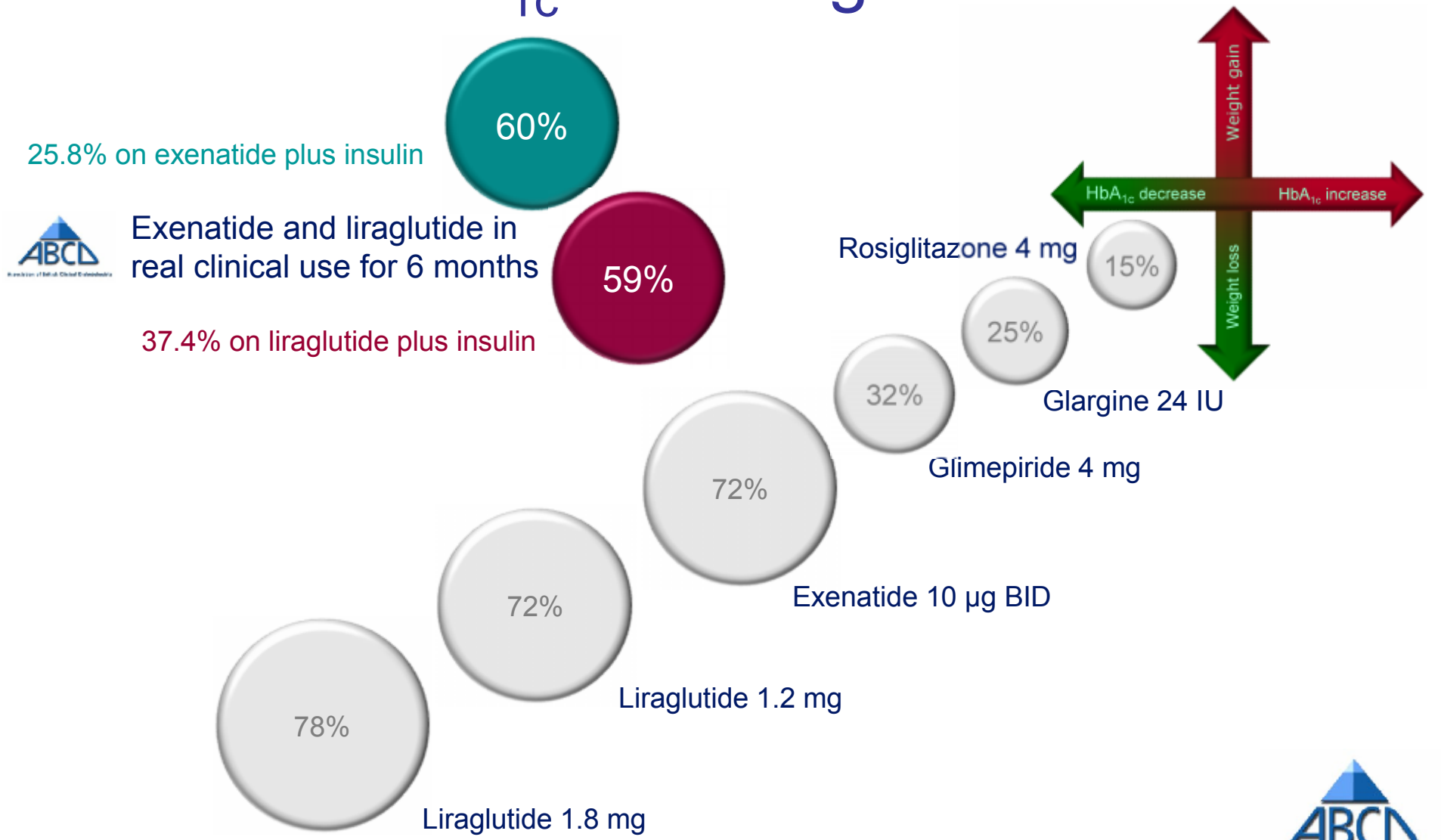
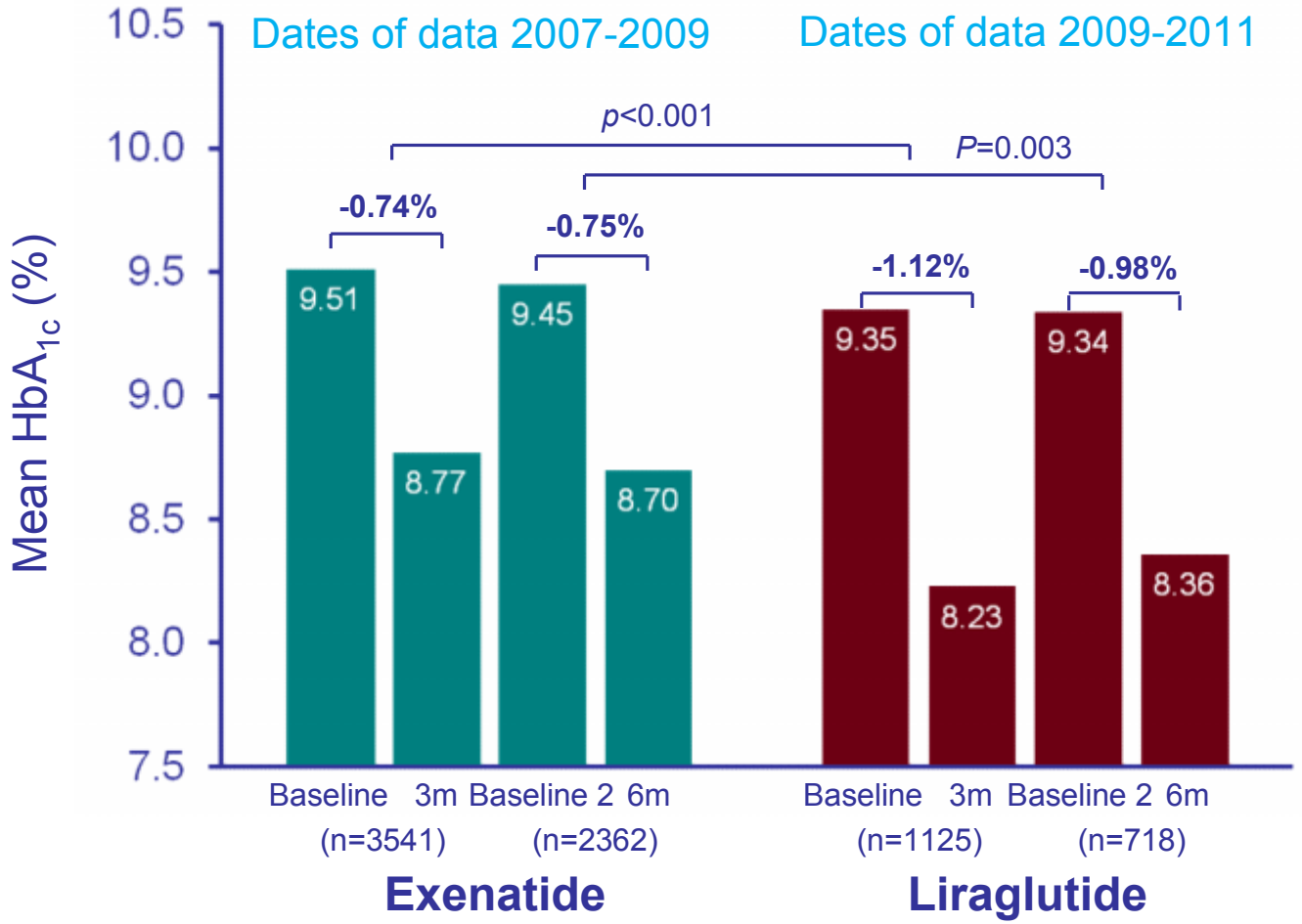
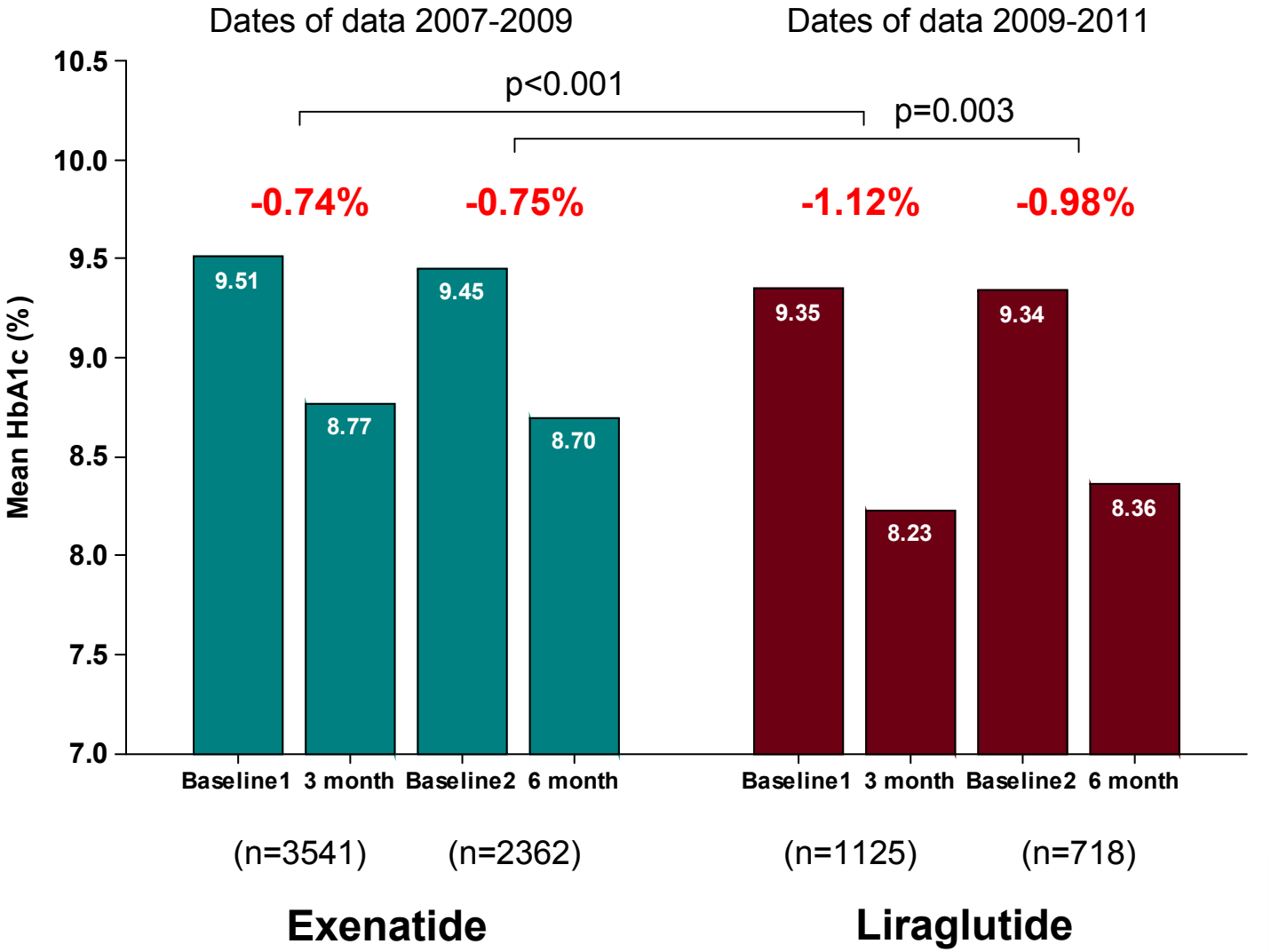


Data on file, Novo Nordisk

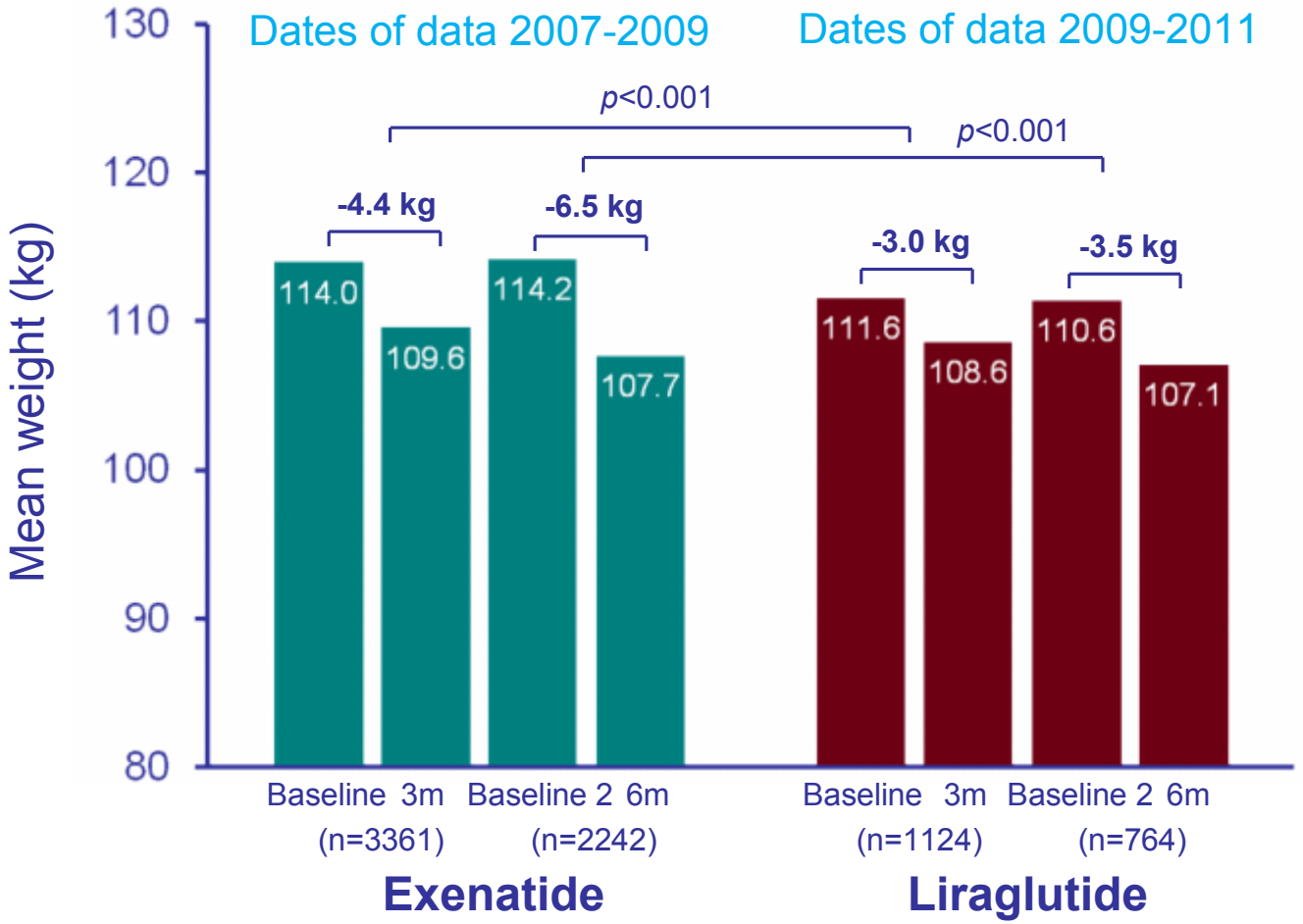
HbA1c results at 3 and 6 months: exenatide and liraglutide



HbA_{1c} results at 3 and 6 months: exenatide and liraglutide



Weight results at 3 and 6 months: exenatide and liraglutide



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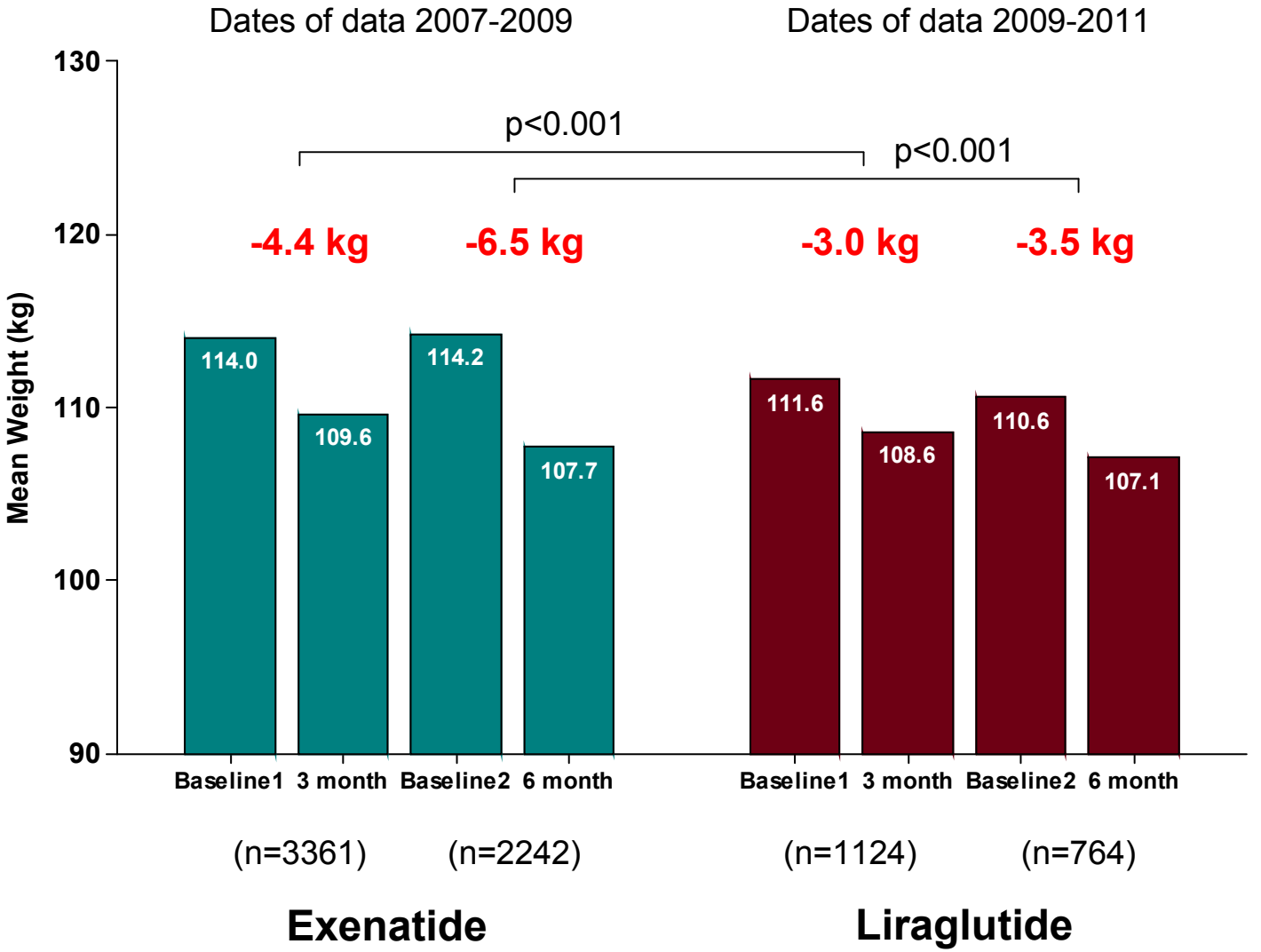
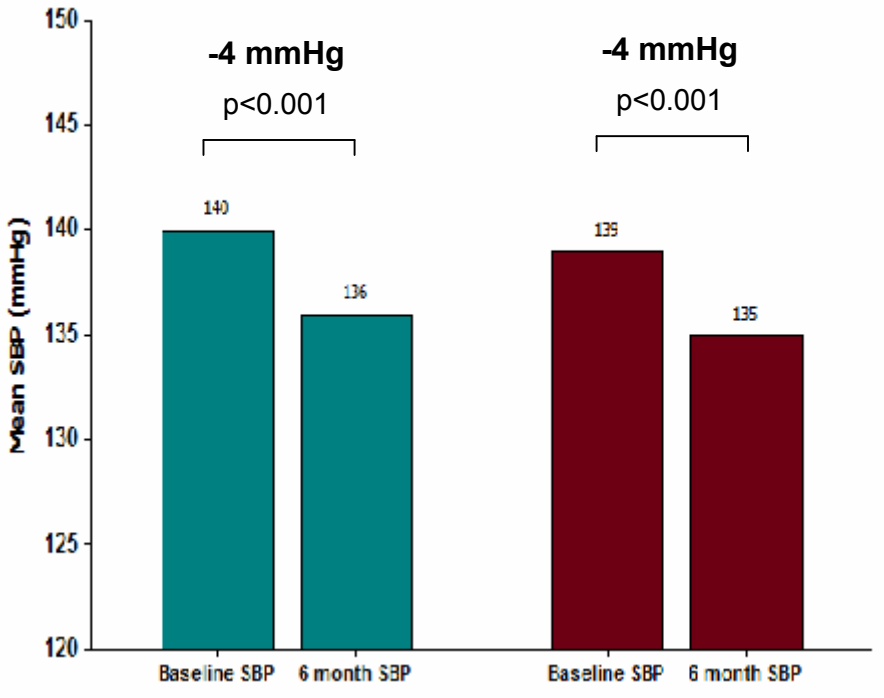


BLOOD PRESSURE AND LIPIDS

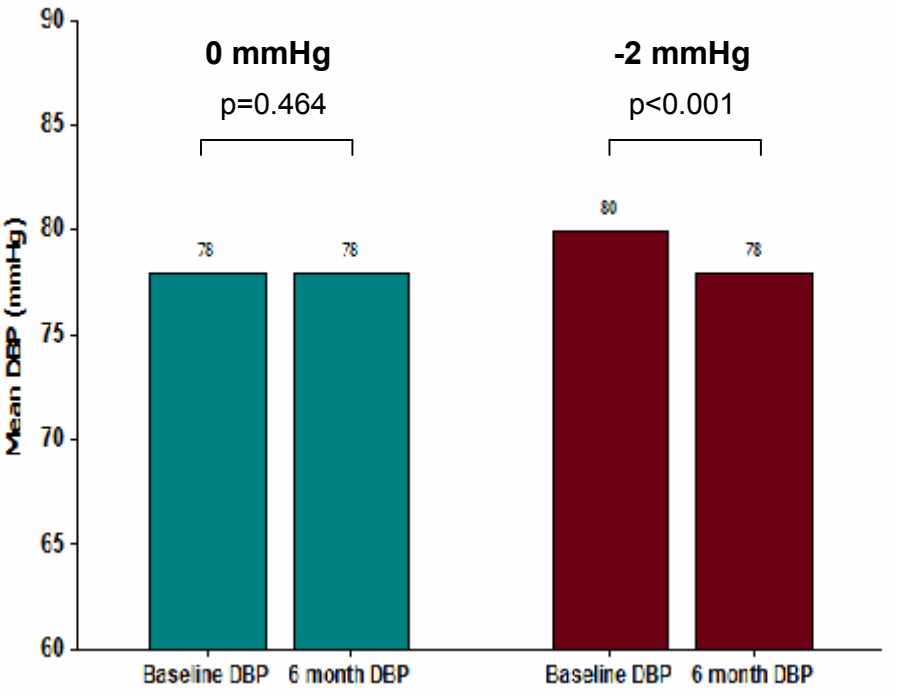
Changes in blood pressure



Exenatide
(n=1246)

Liraglutide
(n=704)

Latest SBP - median 26 weeks



Exenatide
(n=1246)

Liraglutide
(n=704)

Latest DBP - median 26 weeks

Results for exenatide adapted from Ryder *et al. Pract Diab Int* 2010;27:352-357b

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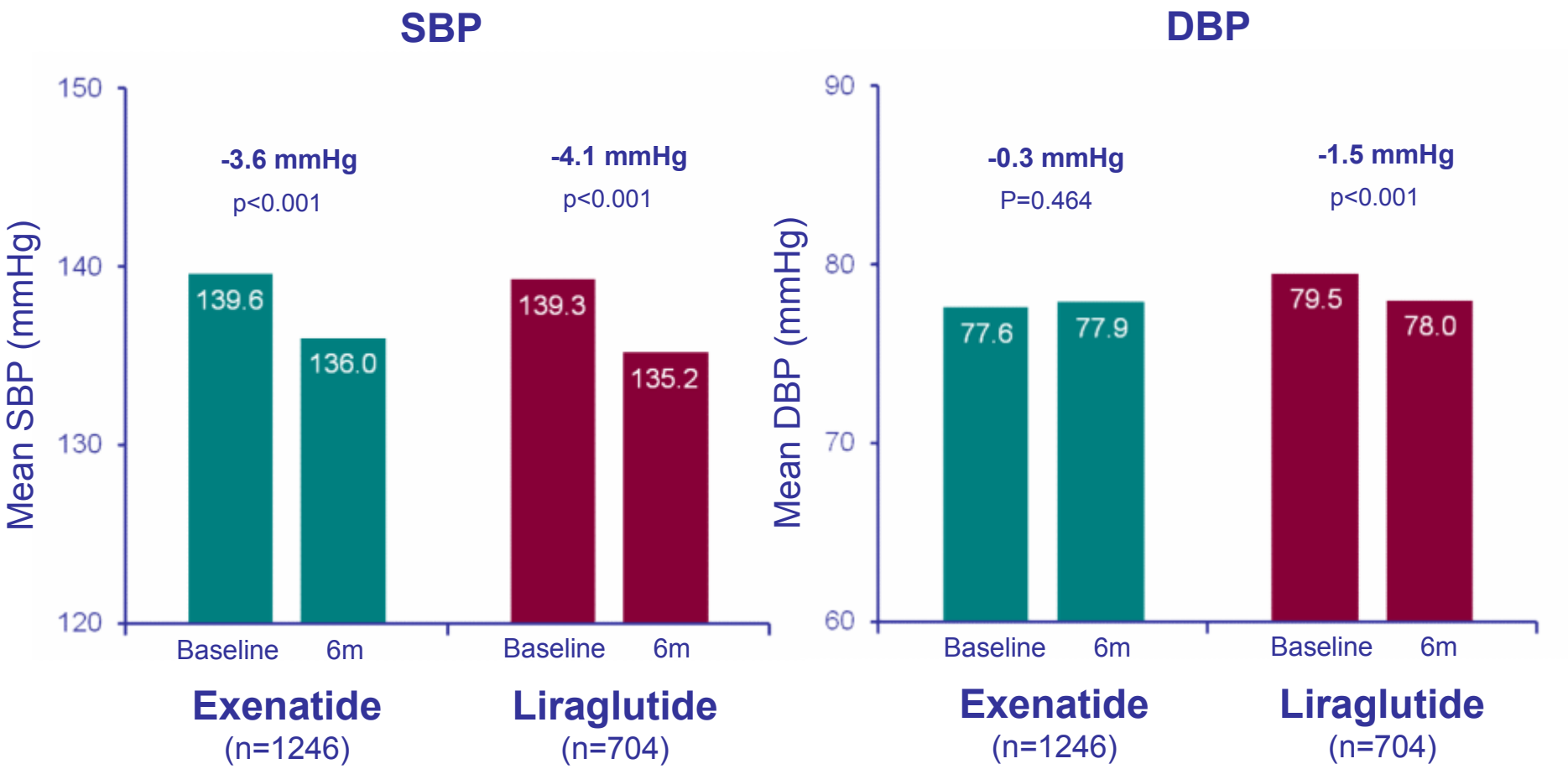
Changes in blood pressure



Latest SBP - median 26 weeks

Results for exenatide adapted from Ryder *et al. Pract Diab Int* 2010;27:352-357b

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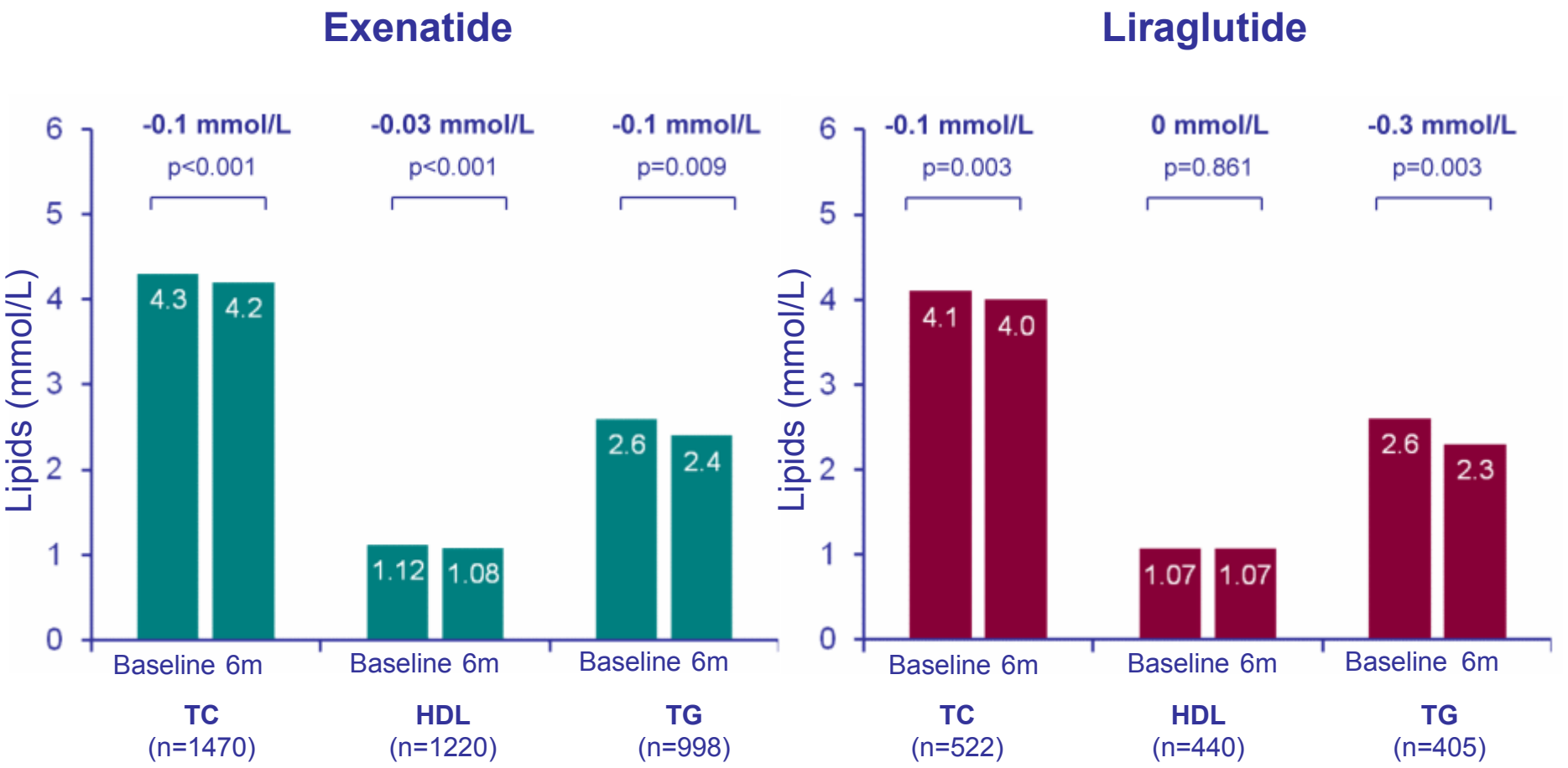
Changes in lipid profiles

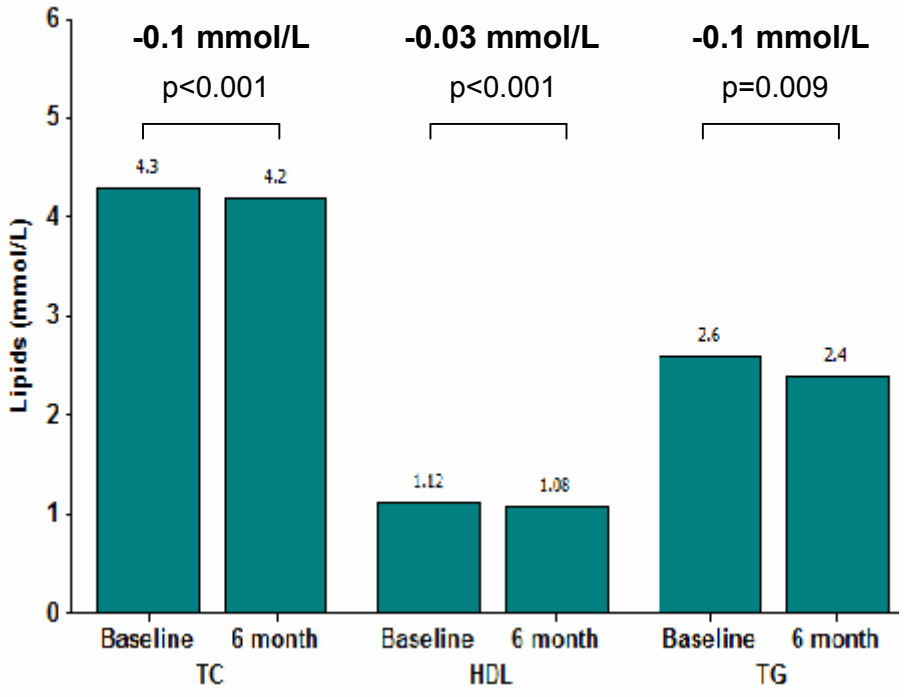


Latest TC, HDL, TG - median 26 weeks

Results for exenatide adapted from Ryder *et al. Pract Diab Int* 2010;27:352-357b

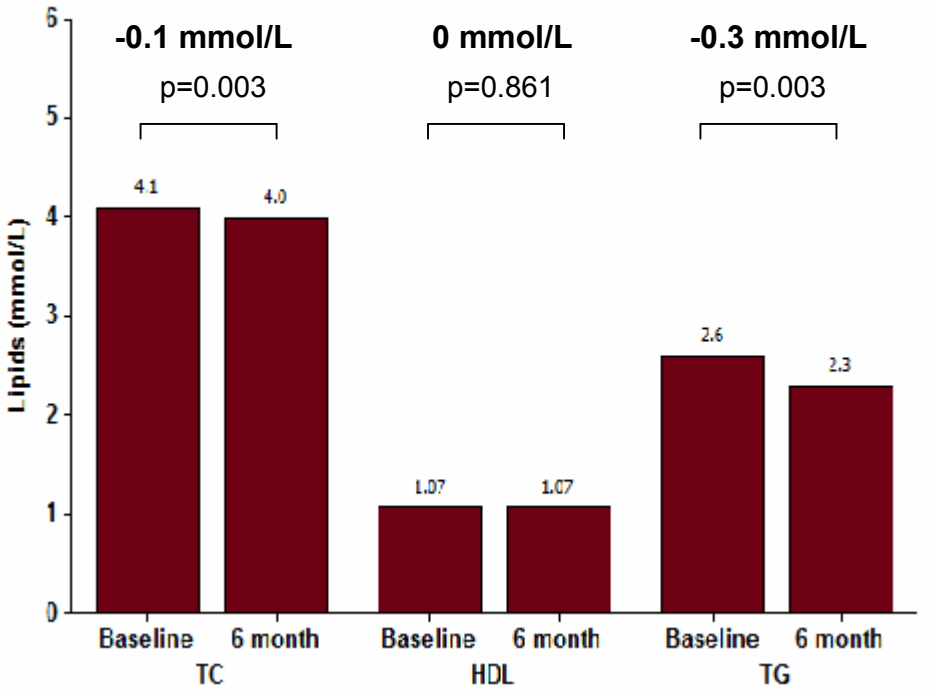
Changes in lipid profiles

Exenatide



TC (n=1470) | HDL (n=1220) | TG (n=998)

Liraglutide



TC (n=522) | HDL (n=440) | TG (n=405)

Latest TC, HDL, TG - median 26 weeks

Results for exenatide adapted from Ryder *et al. Pract Diab Int* 2010;27:352-357b

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Summary of adverse events

Adverse Event	Exenatide audit	Liraglutide audit	
Total GI side effects	23.7%	15.1%	3247 patients
Transient GI side effects	15.6%	10.1%	
Hypoglycaemia	5.6%	0.8%	
Pancreatitis	4 cases (1 no alternate cause)	4 cases (to be clarified)	4129 patients
Acute renal failure	14 cases (0.2%)	3 cases	
Headache	0.8%	0.3%	
Fatigue	0.5%	0.1%	
Dizziness	0.2%	0.1%	
Injection site problems	0.1%	0.2%	
Allergic reaction	0.2%	0.2%	
Thyroid	Not ascertained	1 hyperthyroidism, 1 benign thyroid adenoma	
Bleeding	Not ascertained	3 epistaxis, 1 GI, 1 GI+GU	
Raised LFT	Not ascertained	5 cases	

Results for exenatide adapted from Ryder *et al. Pract Diab Int* 2010;27:352-357b

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Summary of main audit results

- Much heavier and more poorly controlled patients in real clinical practice than in RCTs
- Improvements in blood pressure and lipids
- No new safety concerns
- Differences in HbA_{1c} and weight changes between exenatide and liraglutide

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Differences between exenatide and liraglutide

- Dates of the audit
  - exenatide data: 2007-2009
  - liraglutide data: 2009-2011

- HbA_{1c}
  - exenatide 68.2% v liraglutide 75.8%
- Weight
  - exenatide 89.2% v liraglutide 77.9%

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Reasons for differences

- Drugs
- Patient population/baseline characterstics
- Clinician behaviour

Baseline diabetes treatment use (and discontinuation)

	Exenatide	Liraglutide
Metformin	84.0 (0.9)	83.6 (0.8)
Sulphonylurea	49.5 (6.5)	42.0 (4.9)
Thiazolidinedione	27.1 (13.4)	21.0 (7.4)
Meglitinide	2.0 (0.6)	1.1 (0.3)
Acarbose	0.9 (0.3)	0.6 (0.3)
DPP-4 inhibitor	2.2 (1.4)	12.4 (10.9)
Exenatide	-	20.7 (20.7)
Insulin	33.9 (8.1)	40.2 (2.6)

As a percentage of 6717 and 4129 patients respectively

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Explanation for difference in HbA_{1c} and weight effects

- Exenatide and liraglutide data shown side by side – even though NOT head-to-head clinical trials but rather audits undertaken at different times
- Contributors to the audits might have learned from the previous use of exenatide to avoid over-reduction of diabetes treatment when initiating liraglutide

SWITCHING FROM EXENATIDE OR DPP-4 INHIBITOR TO LIRAGLUTIDE

Switch to liraglutide

- Switch from exenatide
  - 855/4129 (20.7%)
- Switch from DPP-4 inhibitor
  - 449/4129 (10.9%), (62/4129 (1.5%) continued)
- Not on incretin-based therapy
  - 2763/4129 (66.9%)
    - Liraglutide as add-on therapy analysed

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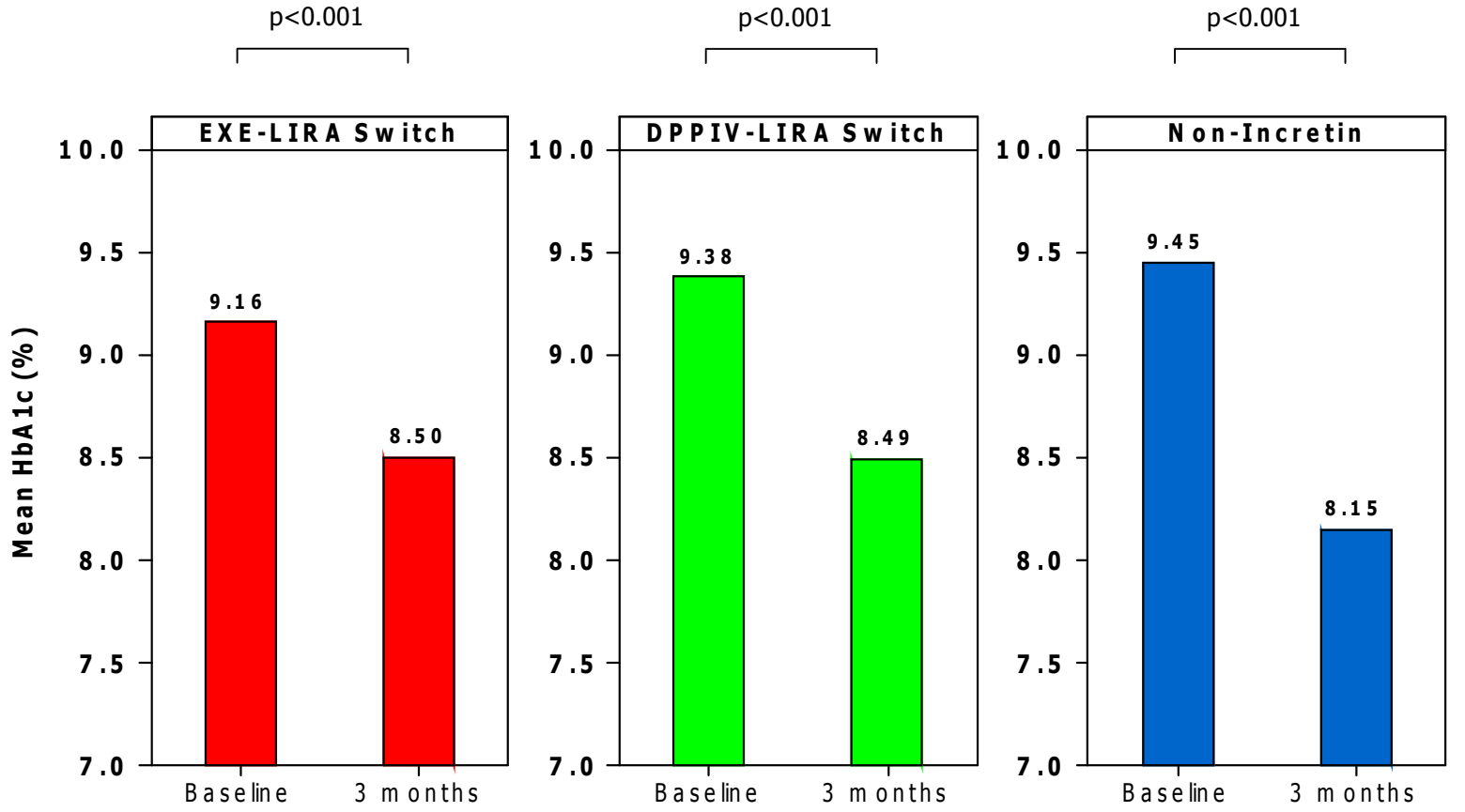
Figure 1: 3 month HbA1c changes of patients switching exenatide BD or DPPIV inhibitors to liraglutide 1.2 mg in comparison with liraglutide add-on therapy



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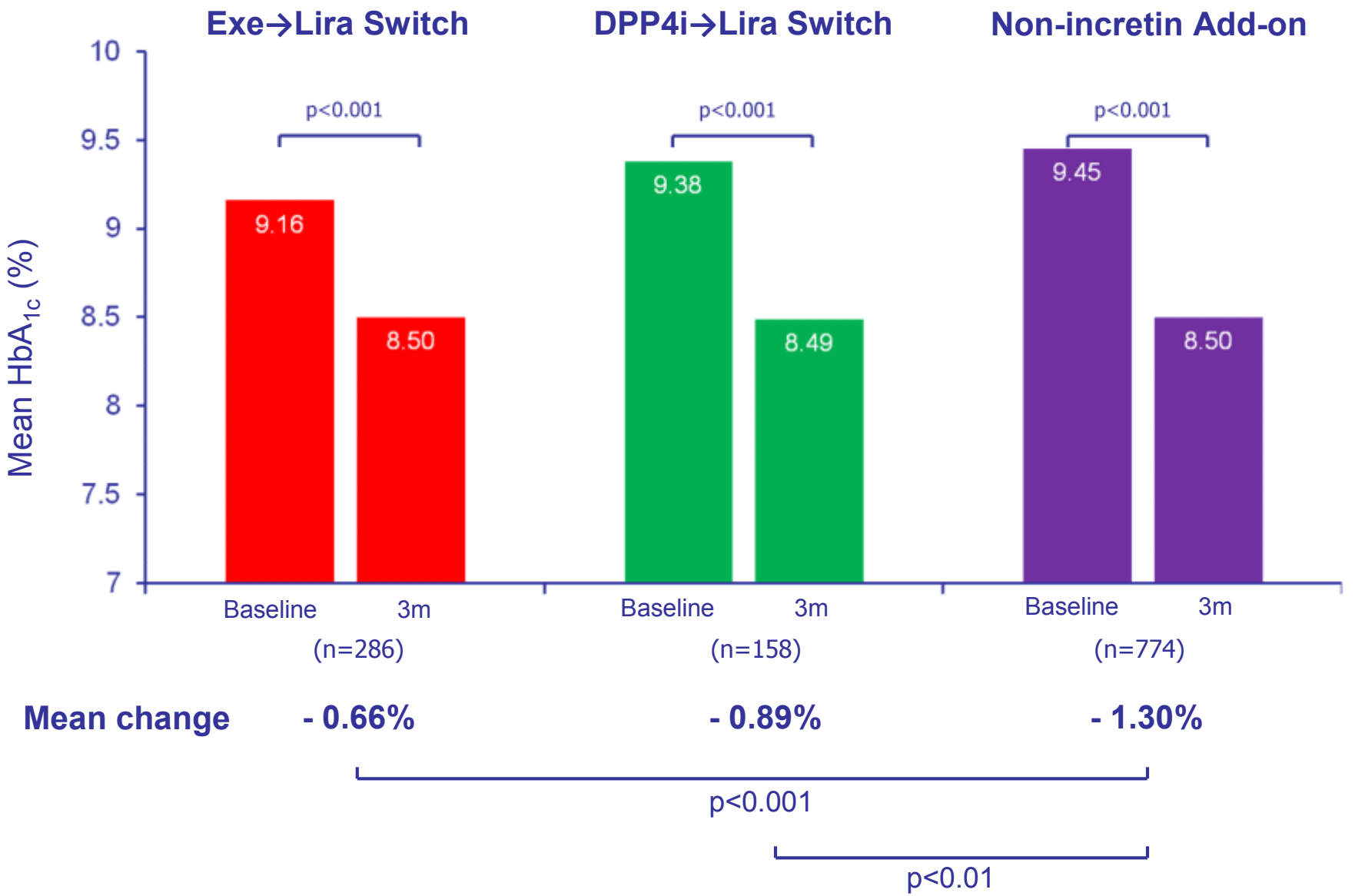
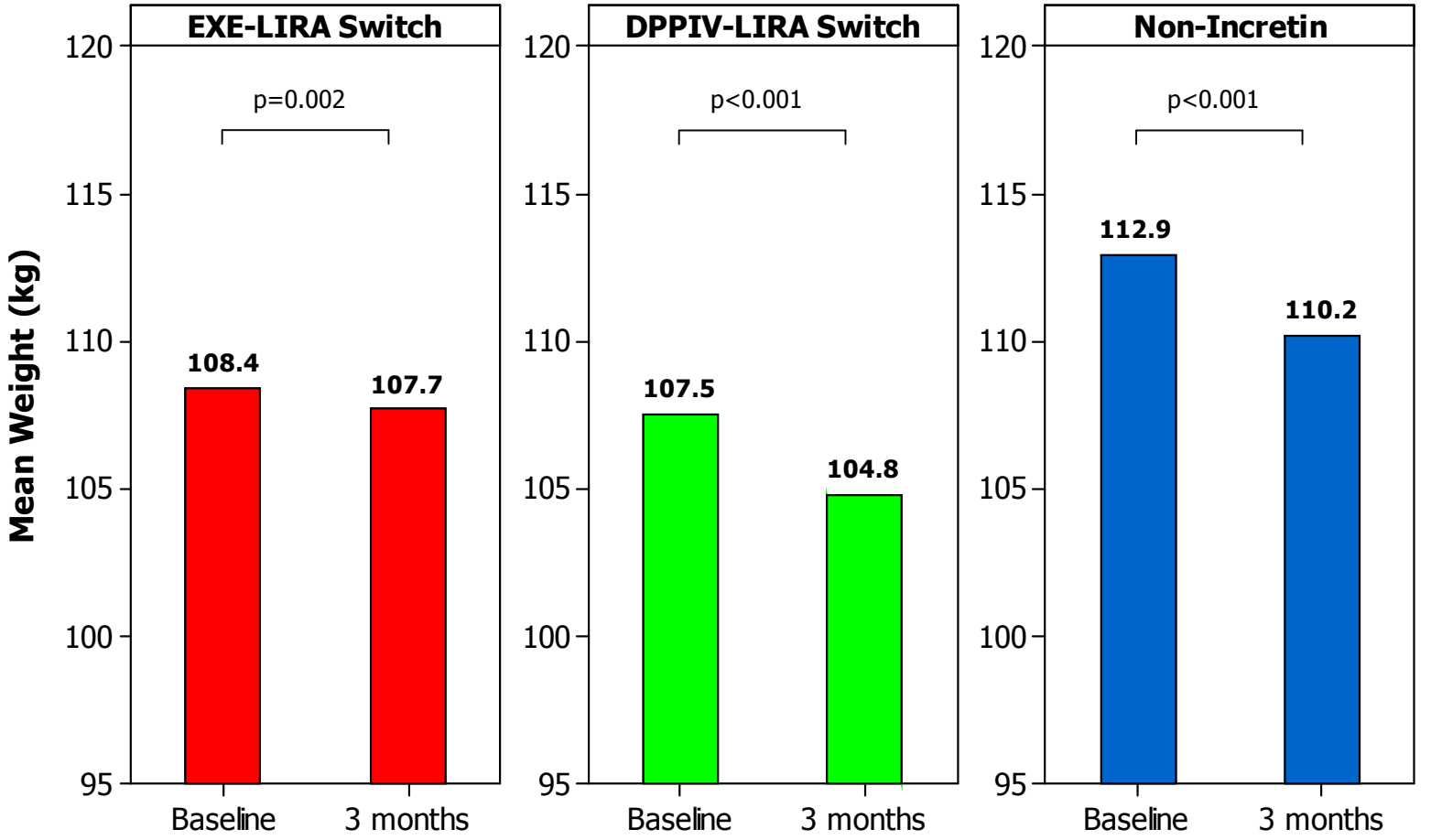


Figure 1: 3 month Weight changes of patients switching exenatide BD or DPPIV inhibitors to liraglutide 1.2 mg in comparison with liraglutide add-on therapy



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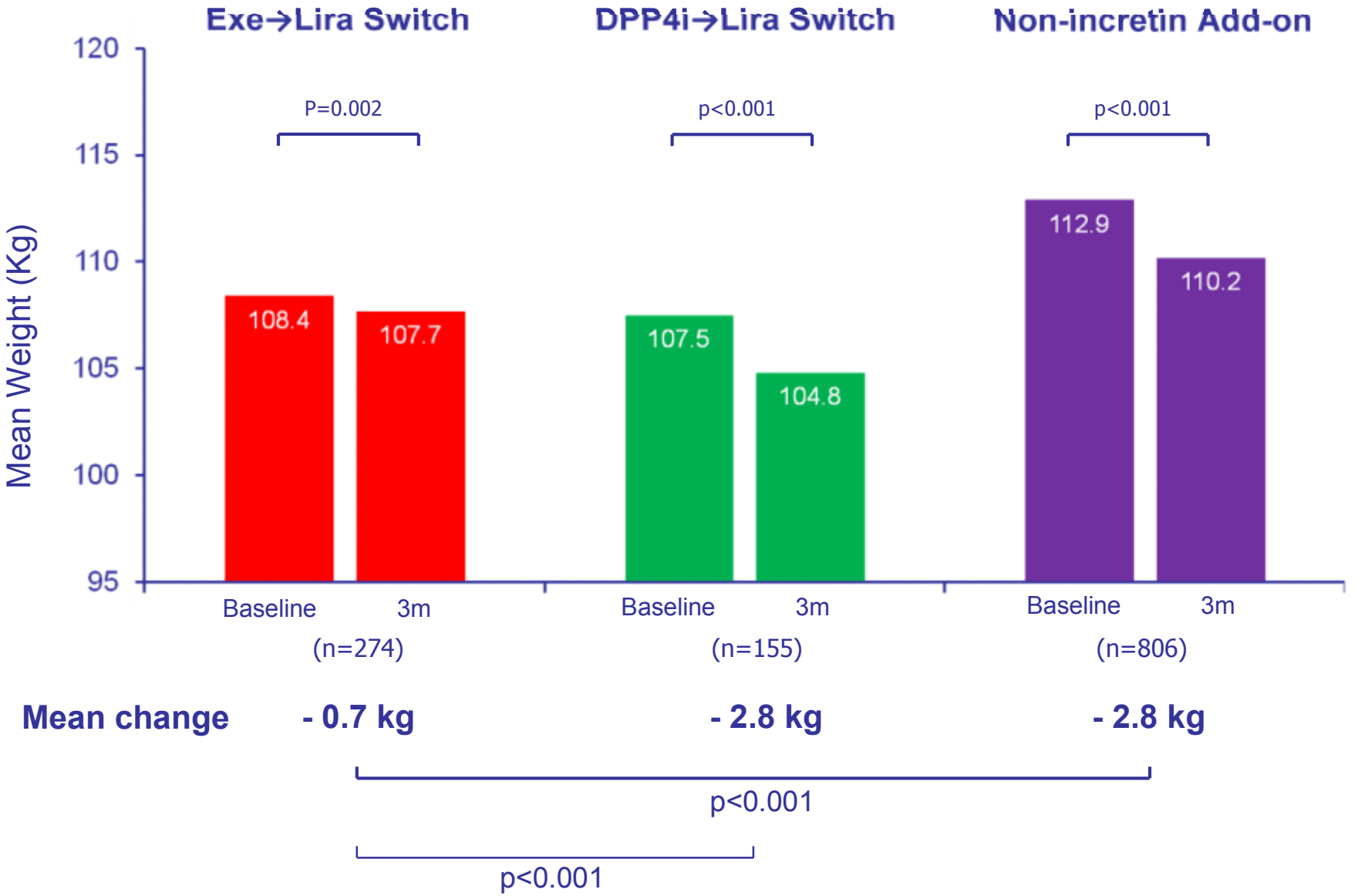

Switching from exenatide to liraglutide

- Improvements in HbA_{1c} and weight are seen when switching from exenatide to liraglutide

Dose of liraglutide used

Total liraglutide audit patients

Exclude on exenatide

Exclude no follow-up data

Dose of liraglutide used

Among 2377, dose at 3 months post-liraglutide initiation:

- Liraglutide 0.6 mg 178/2377 (7.5%)
- Liraglutide 1.2 mg 1748/2377 (73.5%)
- Liraglutide 1.8 mg 186/2377 (7.8%)
- Dose not known 265/2377 (11.1%)

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Baseline characteristics of liraglutide 1.2 mg and 1.8 mg

	Liraglutide 1.2 mg (n=1748)	Liraglutide 1.8 mg (n=186)	*p*-value
Male (%)	55.0	57.5	NS
Caucasian (%)	92.0	82.4	<0.001
Age (yrs)	55.3 (11.0)	55.8 (11.1)	NS
Diabetes duration (yrs)	9 (5-13)	10 (6-14)	0.038
HbA_{1c} (%)	9.38 (1.70)	9.62 (1.83)	NS
Weight (kg)	111.9 (22.6)	113.0 (25.2)	NS
BMI (kg/m^2)	39.3 (7.4)	39.1 (8.0)	NS
On insulin (%)	40.2	50.5	0.007

Age, HbA_{1c}, weight, BMI are reported as mean (SD) and diabetes duration as median (inter-quartile range)

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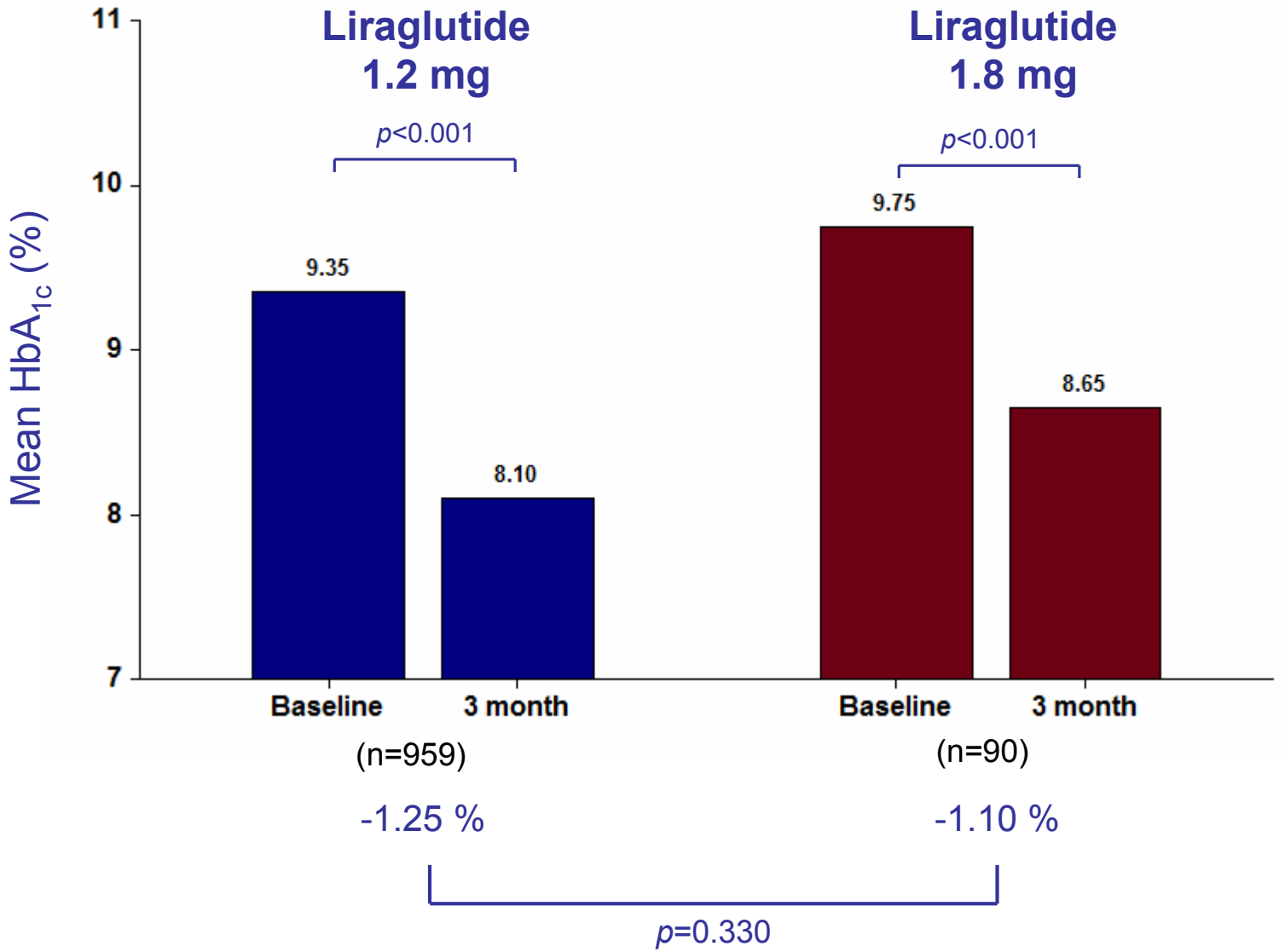
HbA_{1c} outcomes at 3 months: 1.2 mg vs 1.8 mg



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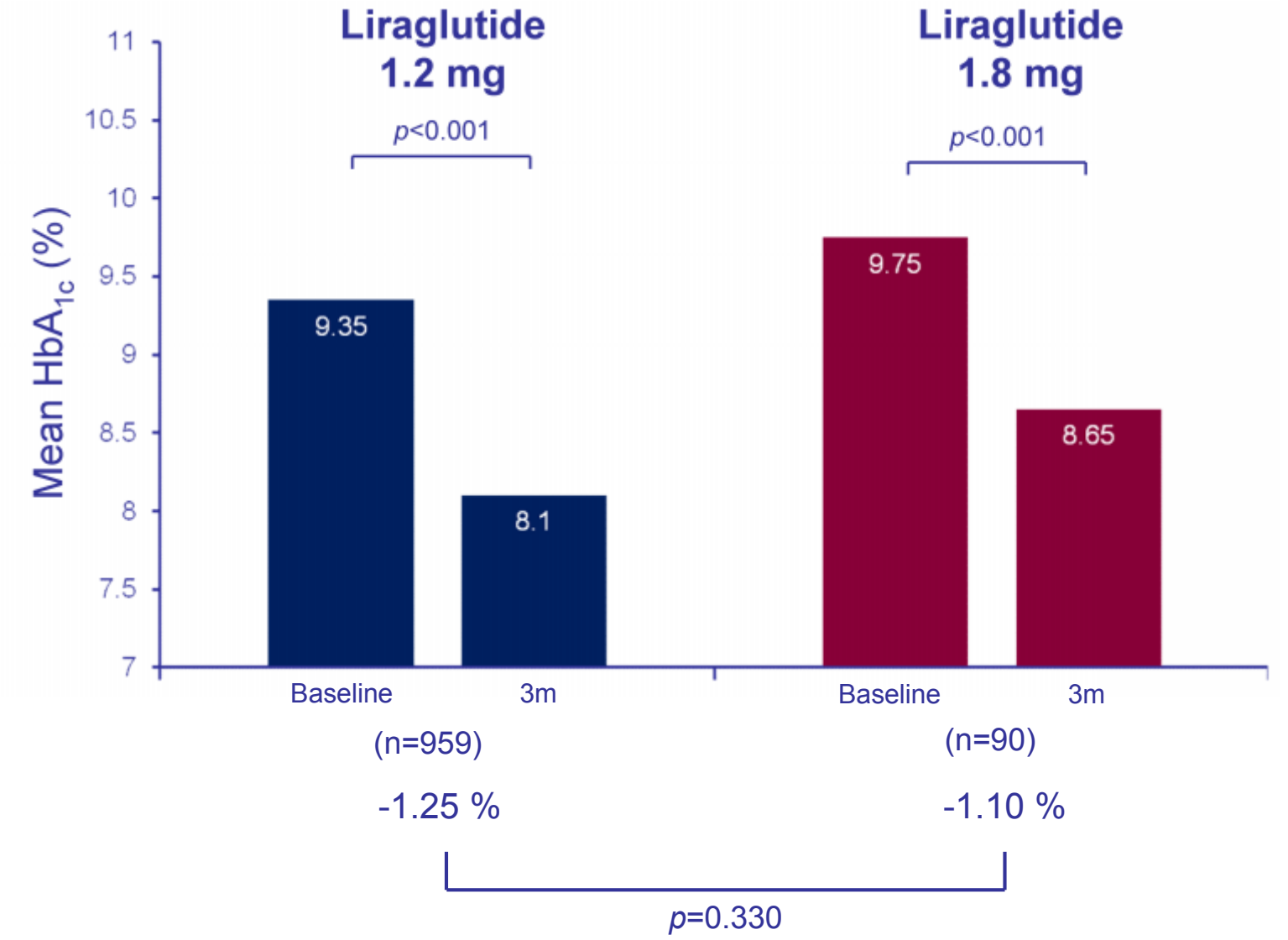
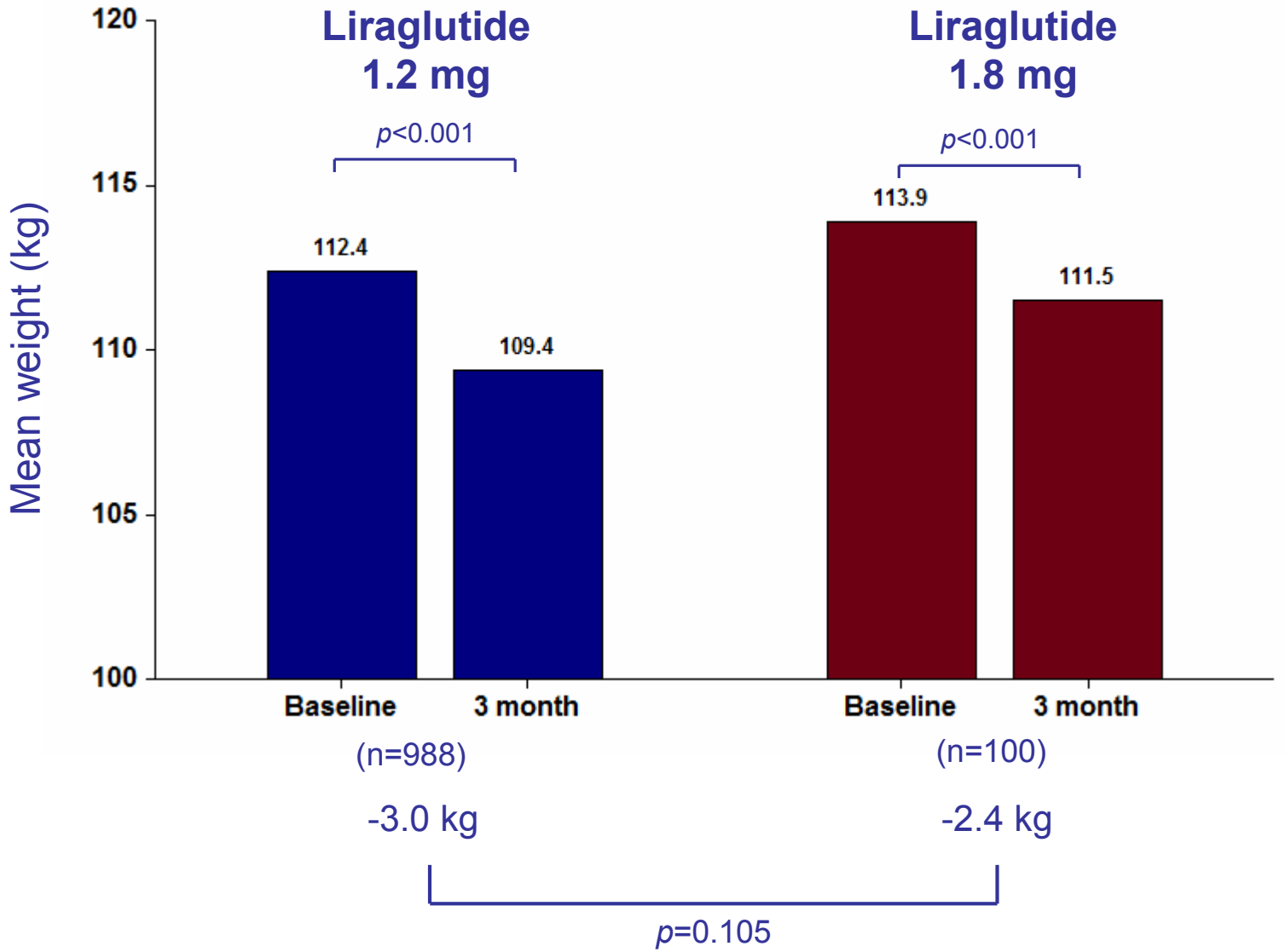


Weight outcomes at 3 months: 1.2 mg vs 1.8 mg



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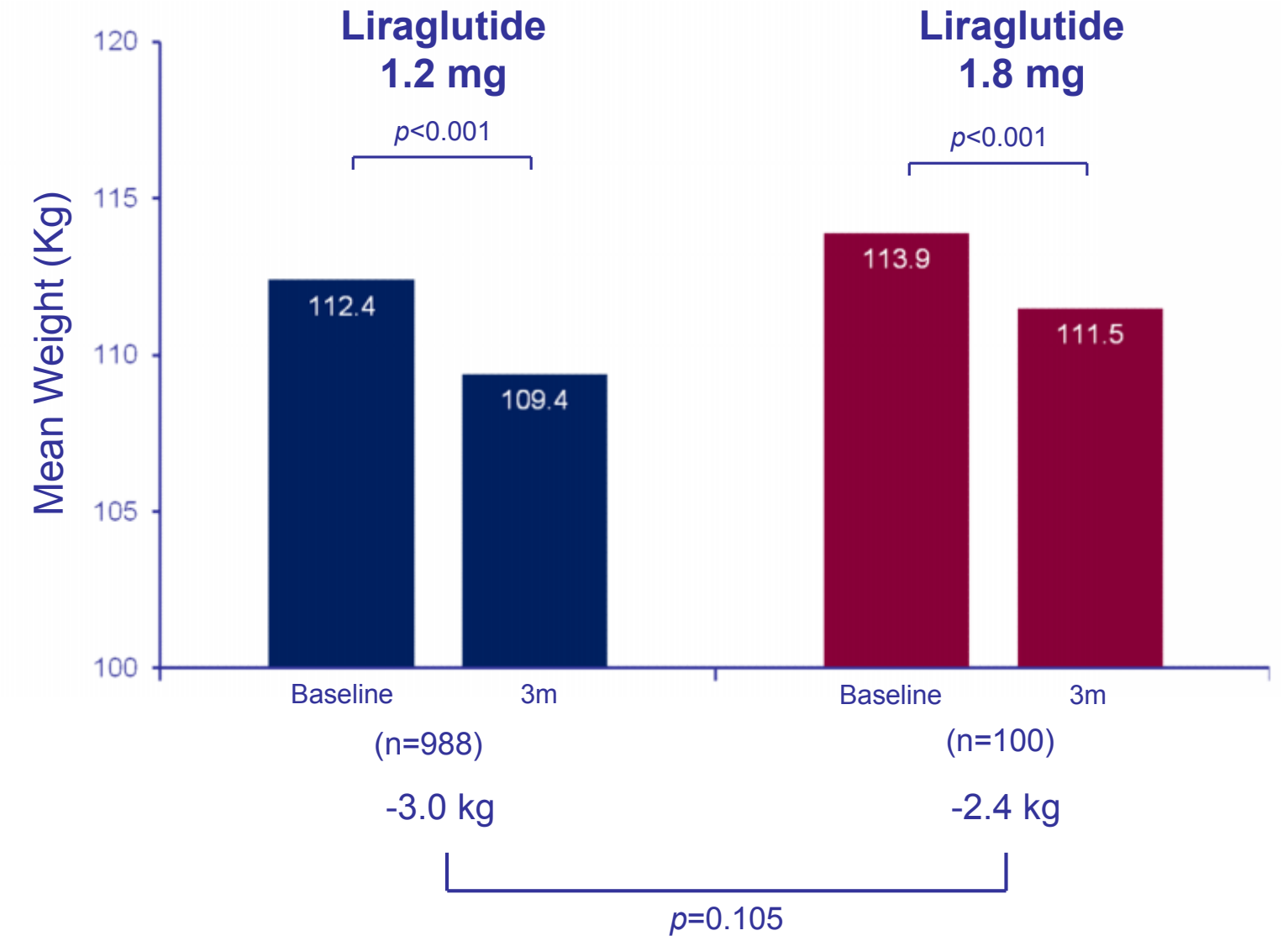

Summary

- Audits provide real life data for GLP-1 therapies in T2DM
- Patients, heavier and more poorly controlled than in RCTs
  - Changes in HbA_{1c}, weight, BP and lipids reflect RCT data
- Differences between exenatide and liraglutide likely reflect differences in cohorts and experience of GLP-1 RA use (but note of caution)
- HbA_{1c} and weight benefits when switching from other incretin-based therapies to liraglutide
- Prescribing outside guidelines

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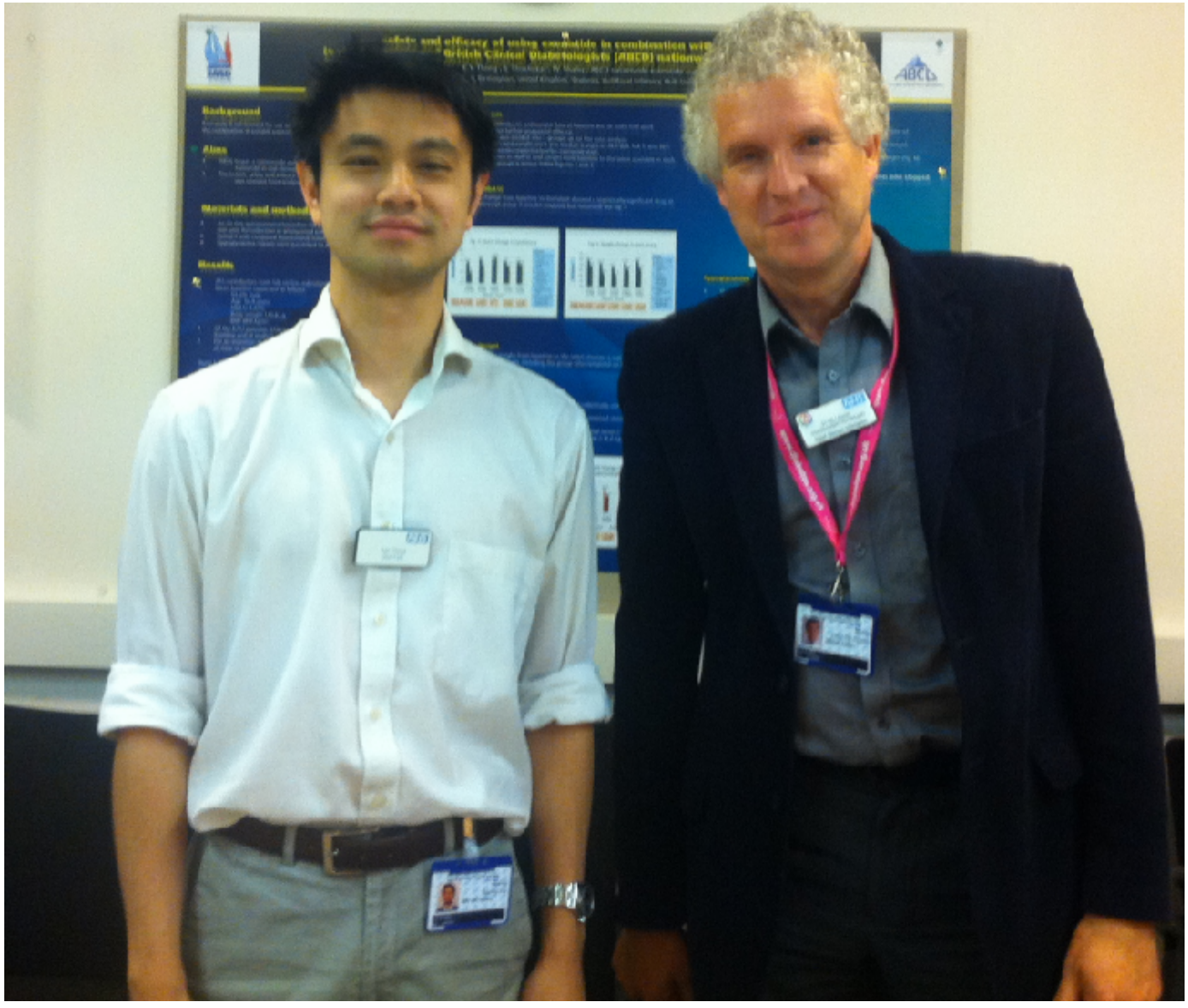

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