The ABCD Nationwide Exenatide and Liraglutide Audits

Dr Marc Evans & Dr Chris Walton
on behalf of
the Association of
British Clinical Diabetologists
Nationwide Audit Contributors

Disclosures

- Design, conduct, analysis and reporting of audits performed by ABCD independently. 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 Walton's declaration

  During the last 5 years Dr Walton has received sponsorship to attend international conferences from Boehringer Ingelheim, Eli Lilly, Novo Nordisk and Takeda UK

  No board or speaker payments from these companies during last 5 years
- Dr Evans' declaration

  During the last 5 years Dr Evans has received research sponsorship and honoraria from Novo Nordisk, Eli Lilly, sanofi, Novartis, BMS, Astra Zeneca and MSD

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The ABCD Nationwide GLP-1 Audit Programme

BACKGROUND
REASONS FOR DOING AUDIT

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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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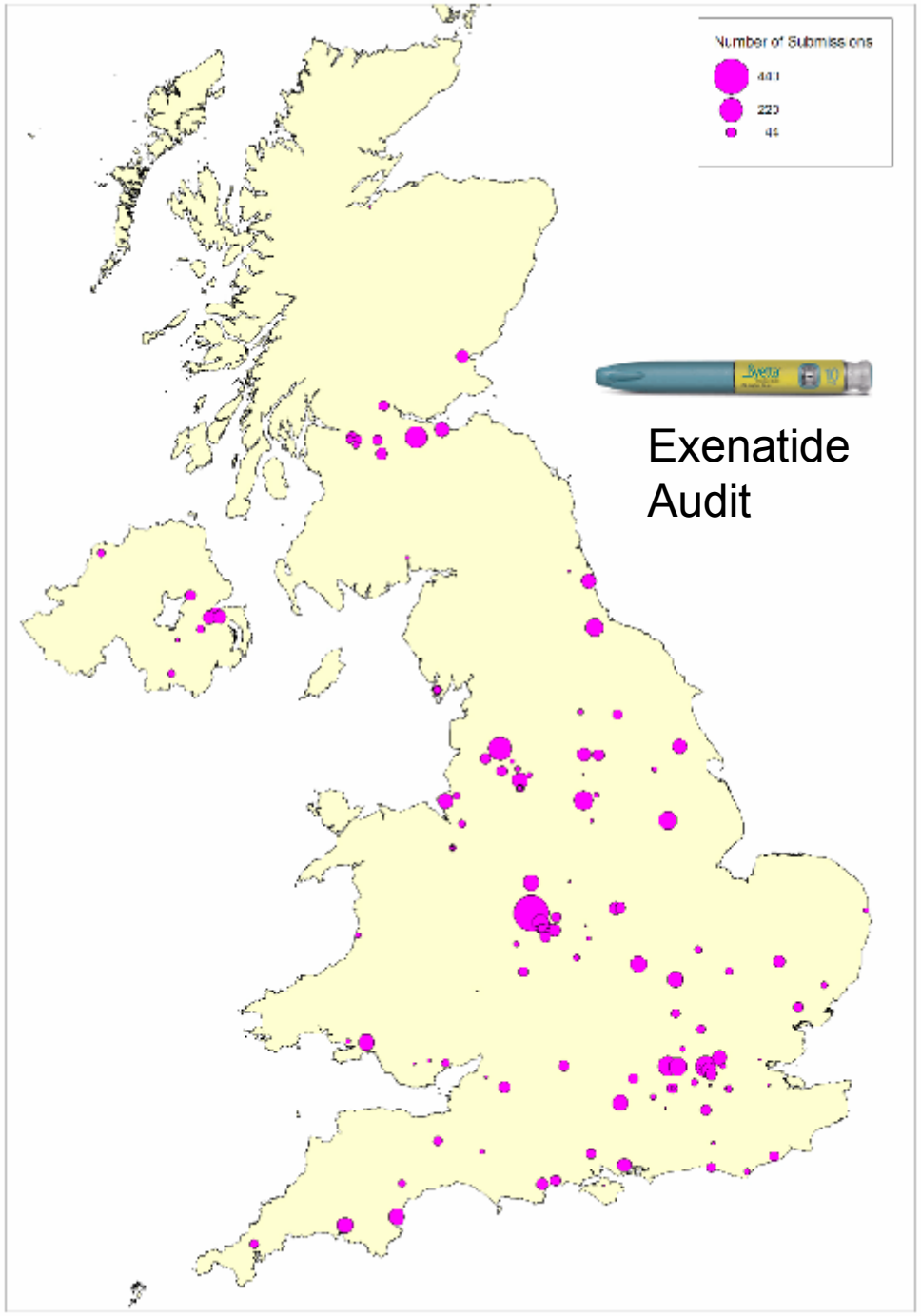
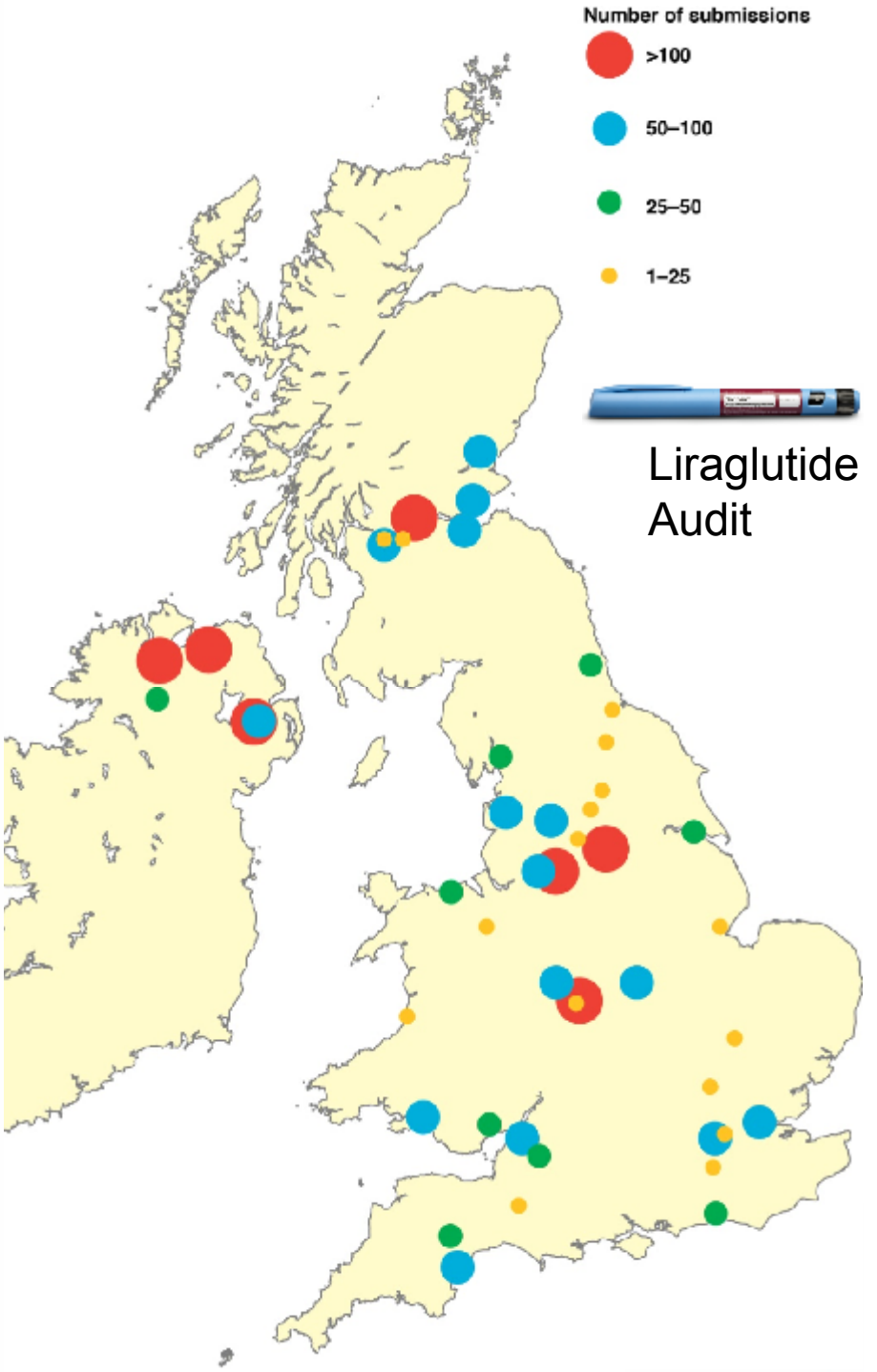


Exenatide Audit



Liraglutide Audit

Audit characteristics

	Exenatide Audit	Liraglutide Audit
Launch date	December 2008	November 2009
Data collection	Online questionnaire or emailed spreadsheet	Downloaded audit tool, email of csv files
Contributors	315	*210*
Centres	126	*64*
Patients	6717	*3010*
Duration of follow-up: median (range)	32 (0.1-175) weeks	*Ongoing*
Status	Primary analyses completed, long term follow-up planned	*Audit recently started*

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Baseline characteristics

	Exenatide Audit	Liraglutide Audit	p value
n	6717	*2303 (from 3010)*	
Male (%)	54.9	*54.1*	ns
Caucasian (%)	84.4	*90.4*	<0.05
Age (yrs)	54.9 (10.6)	*55.4 (11.2)*	ns
Diabetes duration (yrs)	8 (5-13)	*9 (5-13)*	ns
HbA_{1c} (%)	9.47 (1.69)	*9.32 (1.72)*	ns
Weight (kg)	113.8 (23.4)	*111.1 (23.0)*	ns
BMI (kg/m^2)	39.8 (8.0)	*39.1 (7.5)*	ns
Single oral therapy (%)	21.6	*12.0*	<0.01
Dual oral therapy (%)	27.6	*28.1*	ns
≥3 oral therapy (%)	6.5%	*17.9%*	<0.01
On insulin (%)	33.9	*39.8*	<0.01

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

Combination therapy of GLP-1 RAs and insulin is currently not licensed

Baseline diabetes treatment use and discontinuation

	Exenatide Audit	Liraglutide Audit
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%)*
DPPIV Inhibitor	2.2% (1.4%)	*10.9% (9.3%)*
Exenatide	-	*21.9% (21.9%)*
Insulin	33.9% (8.1%)	*39.6% (2.6%)*

Proportion of 6717 and 3010 patients respectively

Combination therapy of GLP-1 RAs and insulin is currently not licensed

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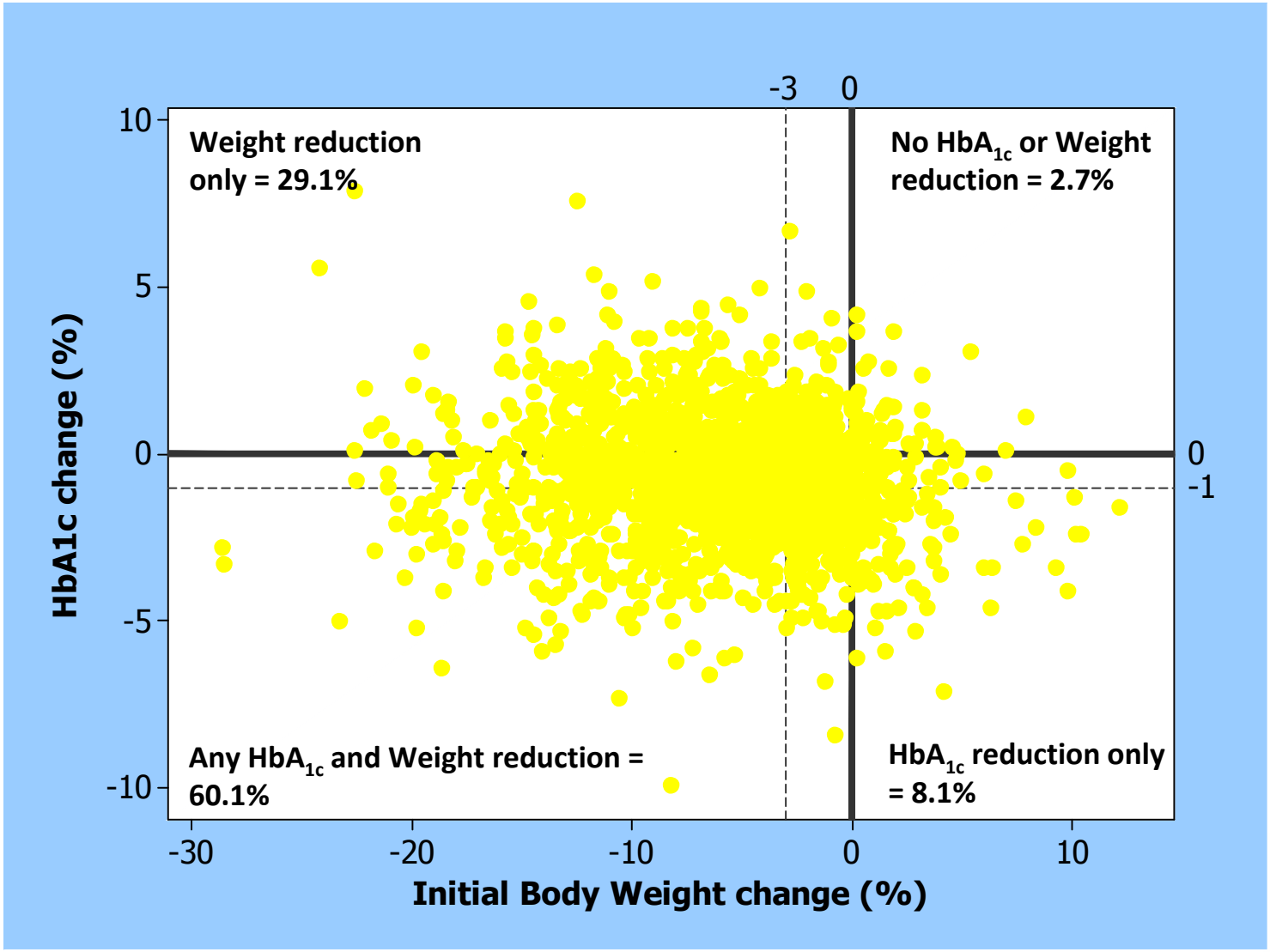
HbA_{1c} and IBW changes at 6 months in 1882 patients on exenatide



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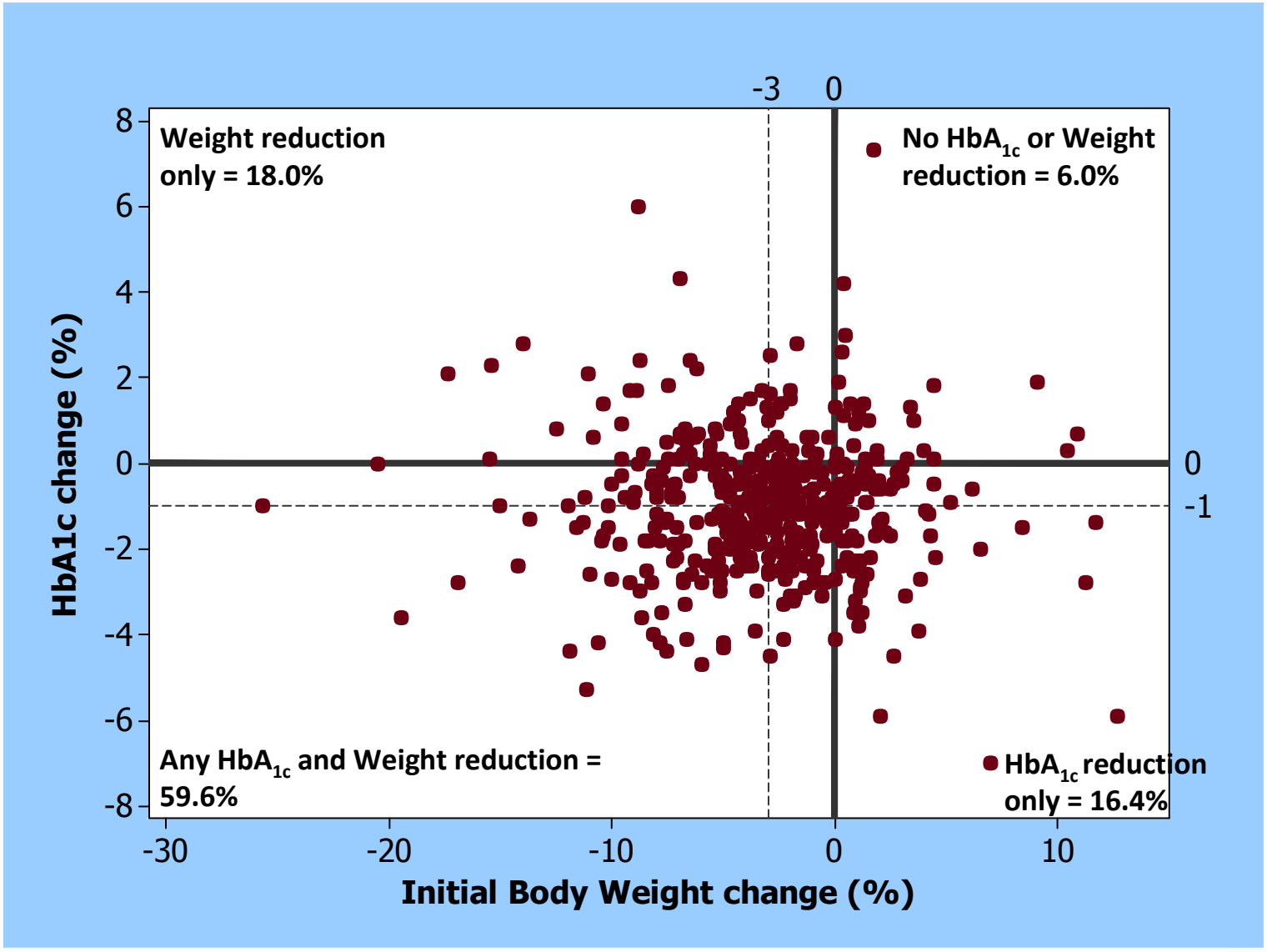
HbA_{1c} and IBW changes at 6 months in 451 patients on liraglutide (excluding those who were on exenatide)



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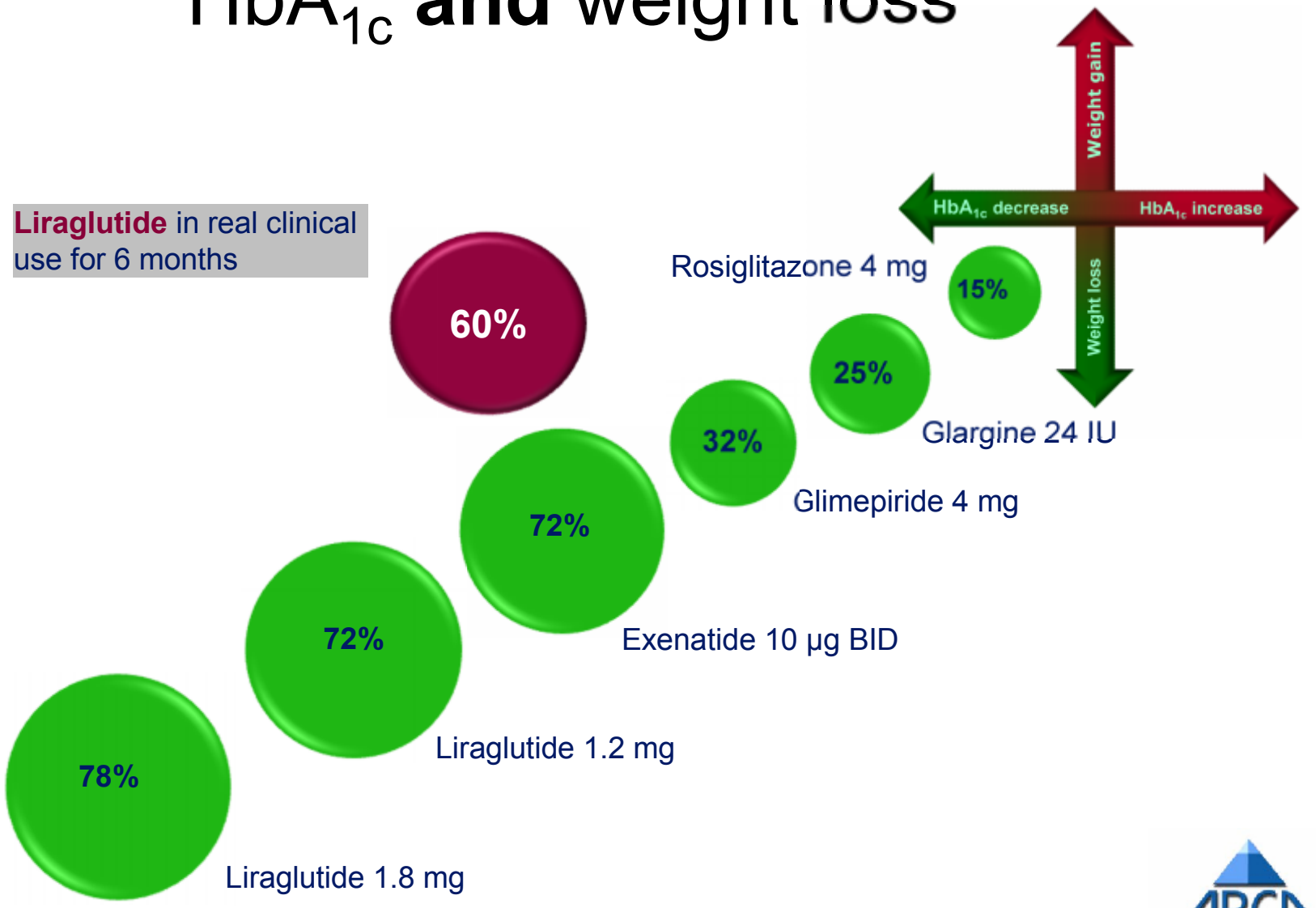
Percentage of subjects achieving fall in HbA_{1c} **and** weight loss

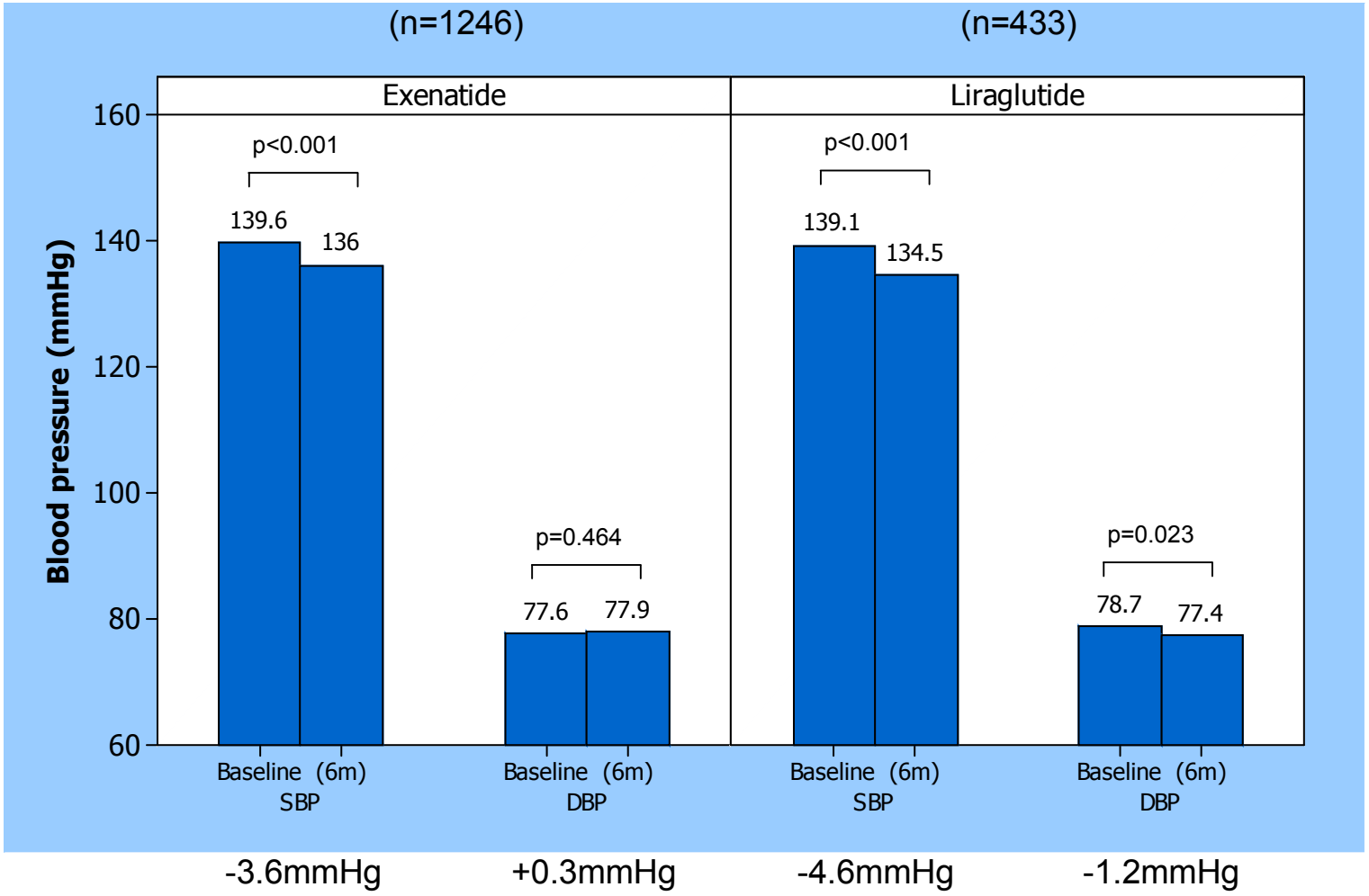
Liraglutide in real clinical use for 6 months



Data on file (Composite Endpoint/01/02), Novo Nordisk

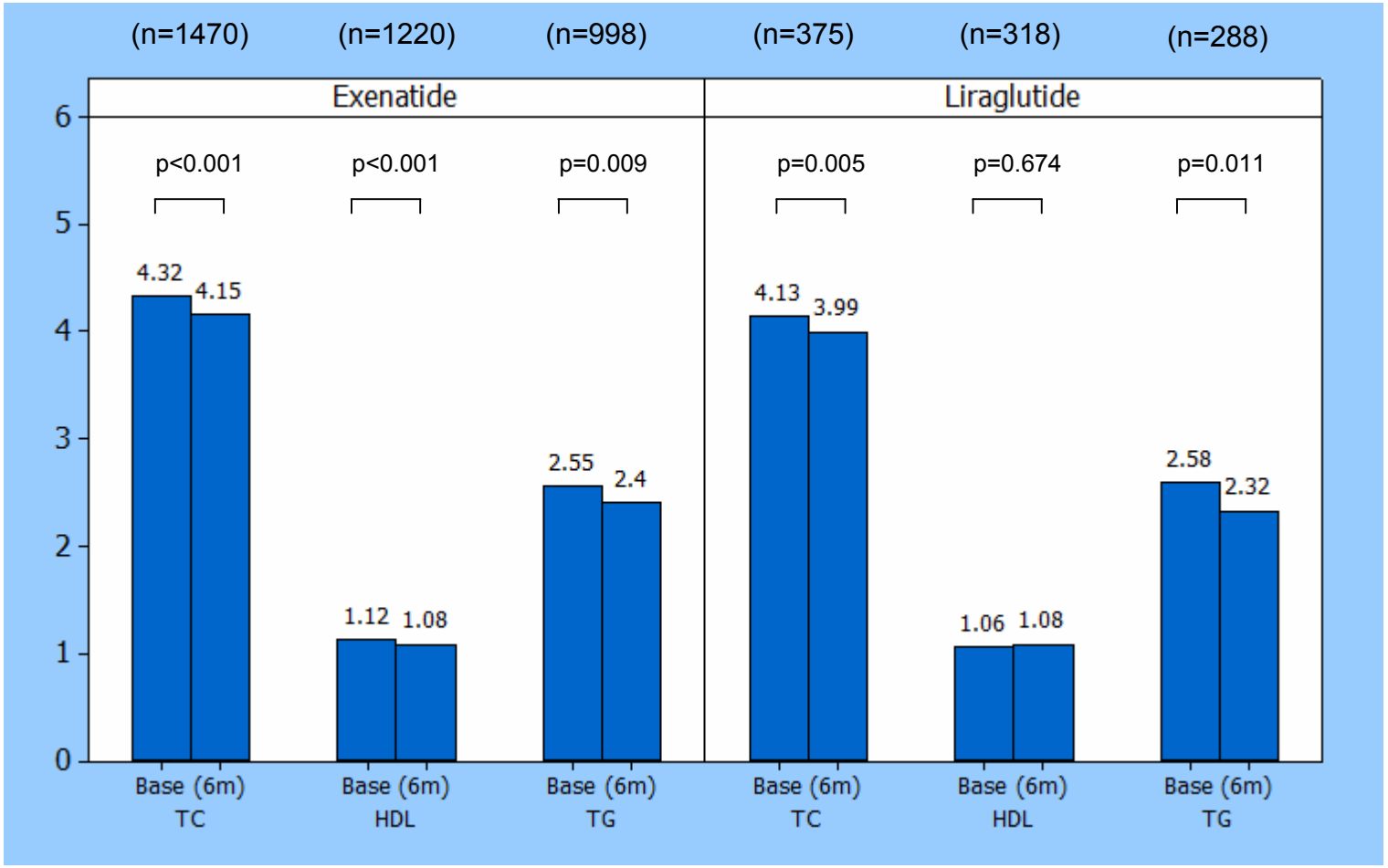
Blood Pressure and Lipids

Blood pressure results: exenatide and liraglutide



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

Lipid results: exenatide and liraglutide



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

Summary of adverse events in patients in the ABCD nationwide exenatide audit

Adverse Event	Total number = 6717	Percentage of total
Total GI side effects	1593	23.7%
Transient GI side effects	*1047*	*15.6%*
*Stopped temporarily**	*62*	*0.9%*
*Stopped permanently**	*484*	*7.2%*
Post-exenatide hypoglycaemia	377	5.6%
Pre-exenatide hypoglycaemia	223	3.3%
Pancreatitis	4	
Acute renal failure	14	
Headache	51	0.76%
Fatigue	35	0.52%
Dizziness	15	0.22%
Injection site problems	8	0.12%
Allergic reaction	13 (5 anaphylaxis)	0.19%

* Due to gastrointestinal (GI) side effects

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Effects of exenatide and gliptin switch to liraglutide

Switch to liraglutide

- Switch from exenatide = 707/3010 (23.5%)
- Switch from DPPIV inhibitor = 317/3010 (10.5%)
- Not on incretin-based therapy = 1986/3010 (66.0%)

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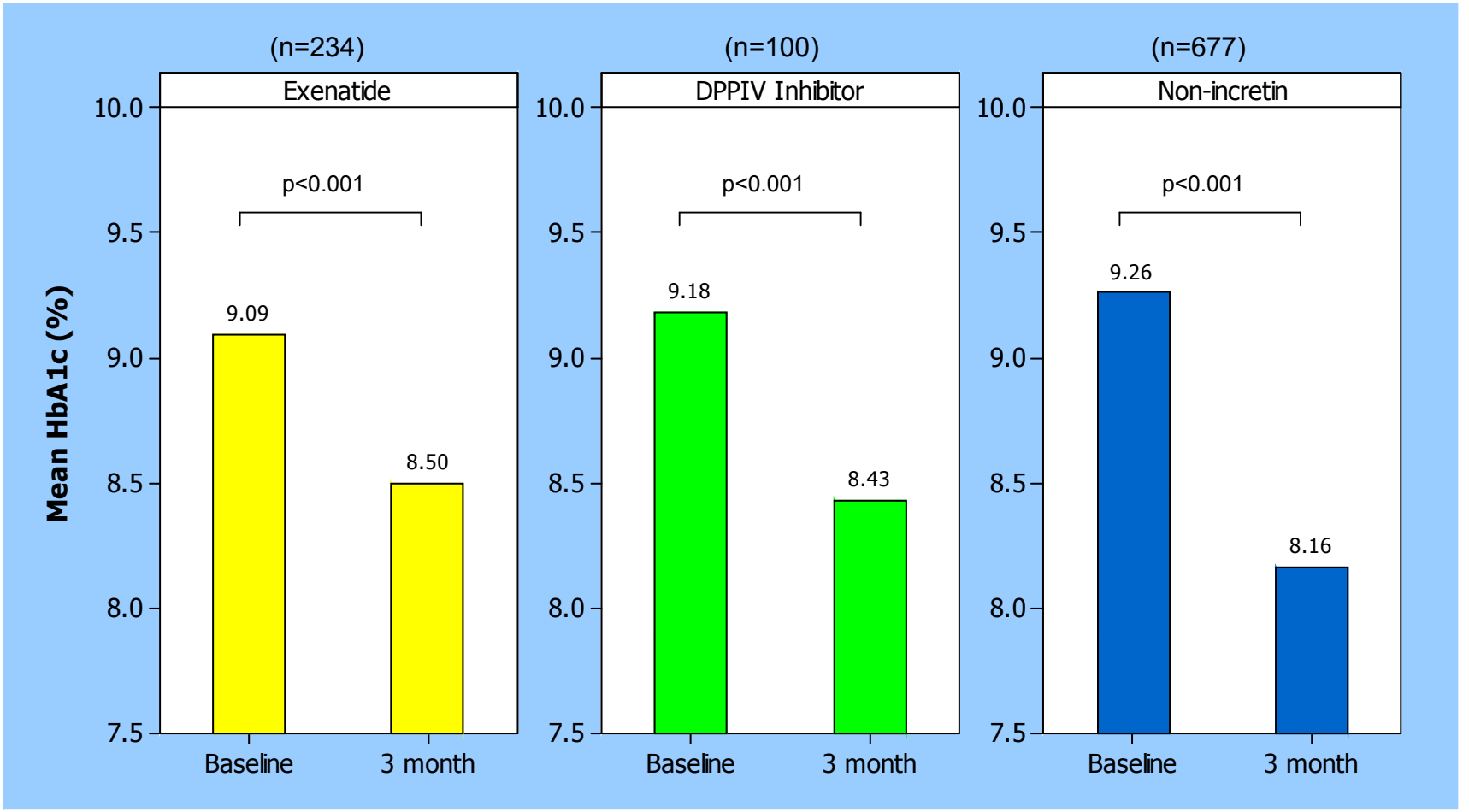
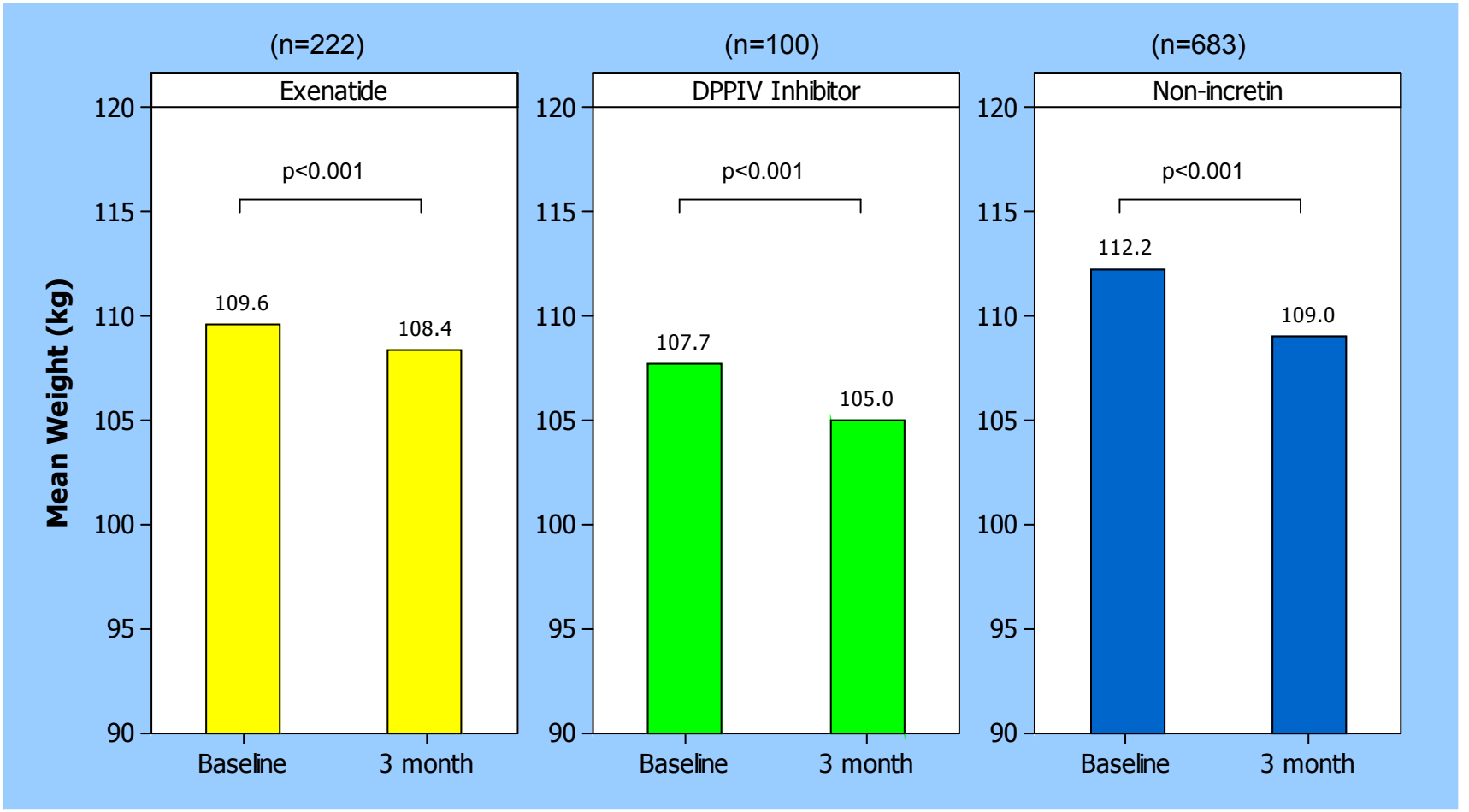
Baseline vs 3 month HbA_{1c} among patients on Exenatide, DPPIV inhibitors and Non-incretin therapies starting liraglutide



Mean change	-0.60%	-0.75%	-1.10%

Baseline vs 3 month Weight among patients on Exenatide, DPPIV inhibitors and Non-incretin therapies starting liraglutide



Mean change

-1.2 kg

-2.8 kg

-3.1 kg

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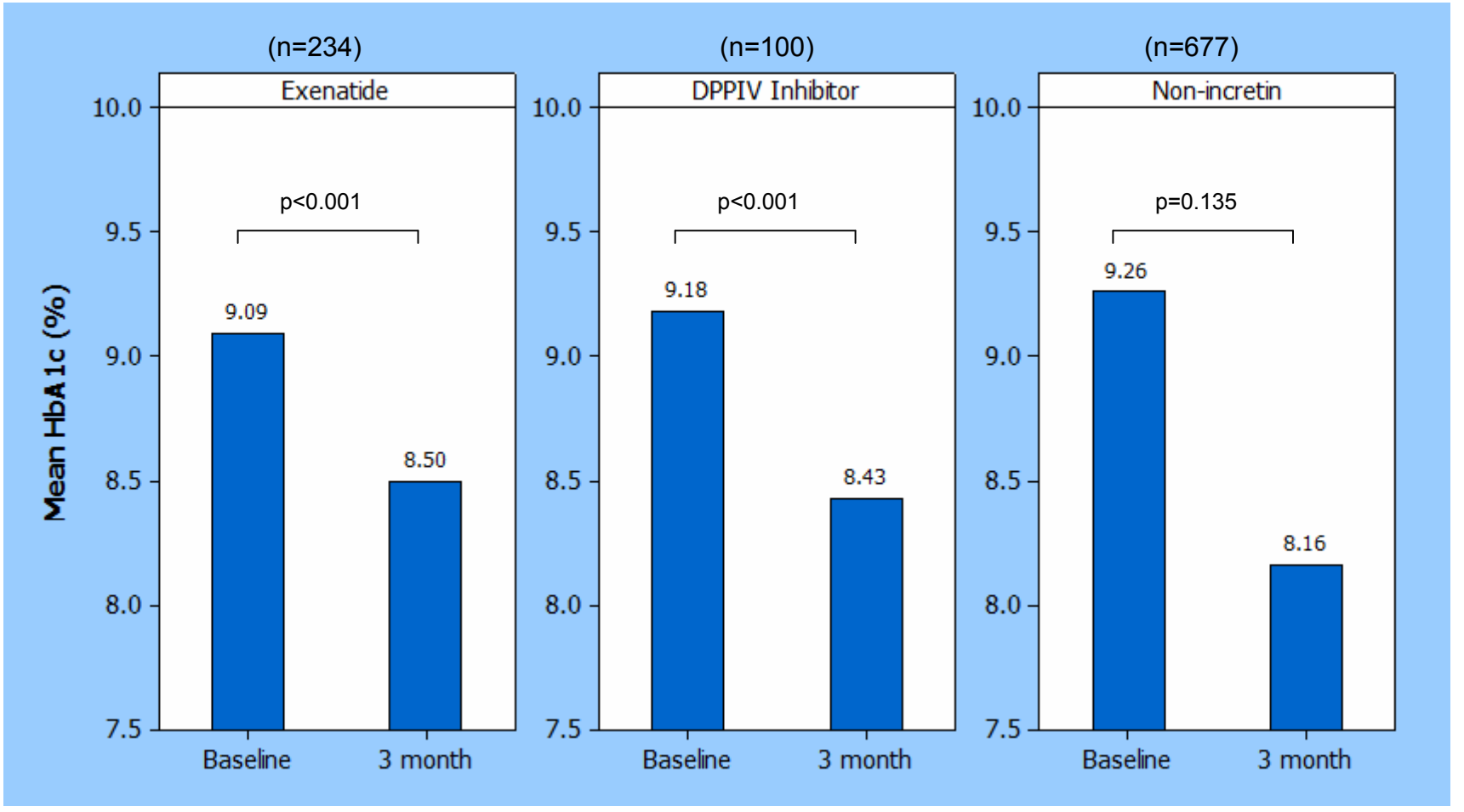
Baseline vs 3 month HbA_{1c} among patients on Exenatide, DPPIV inhibitors and Non-incretin therapies starting liraglutide



Mean change **-0.60%** P<0.001 **-0.75%** P<0.001 **-1.10%** P<0.001

P<0.001 v DPPIV or v non incretin

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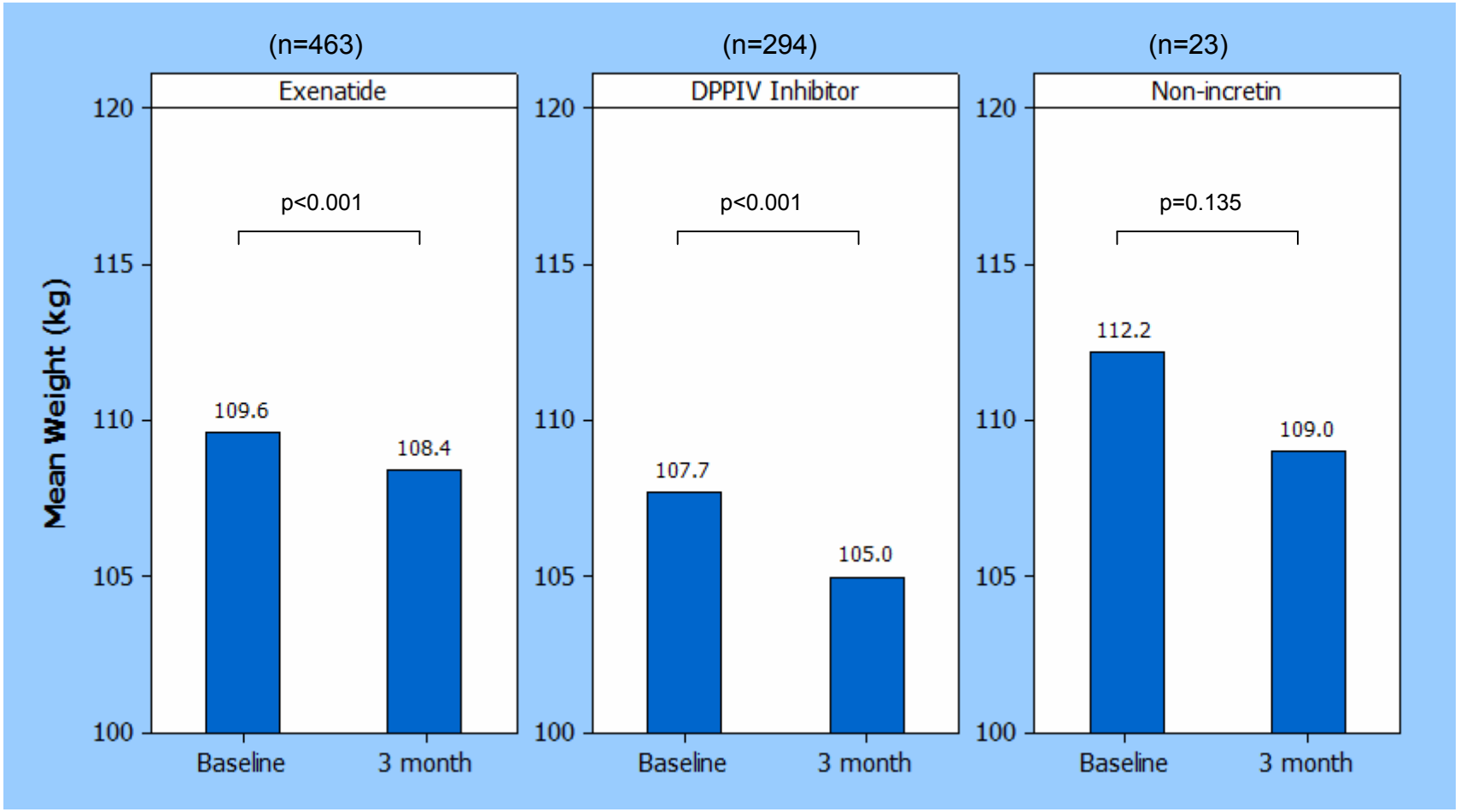
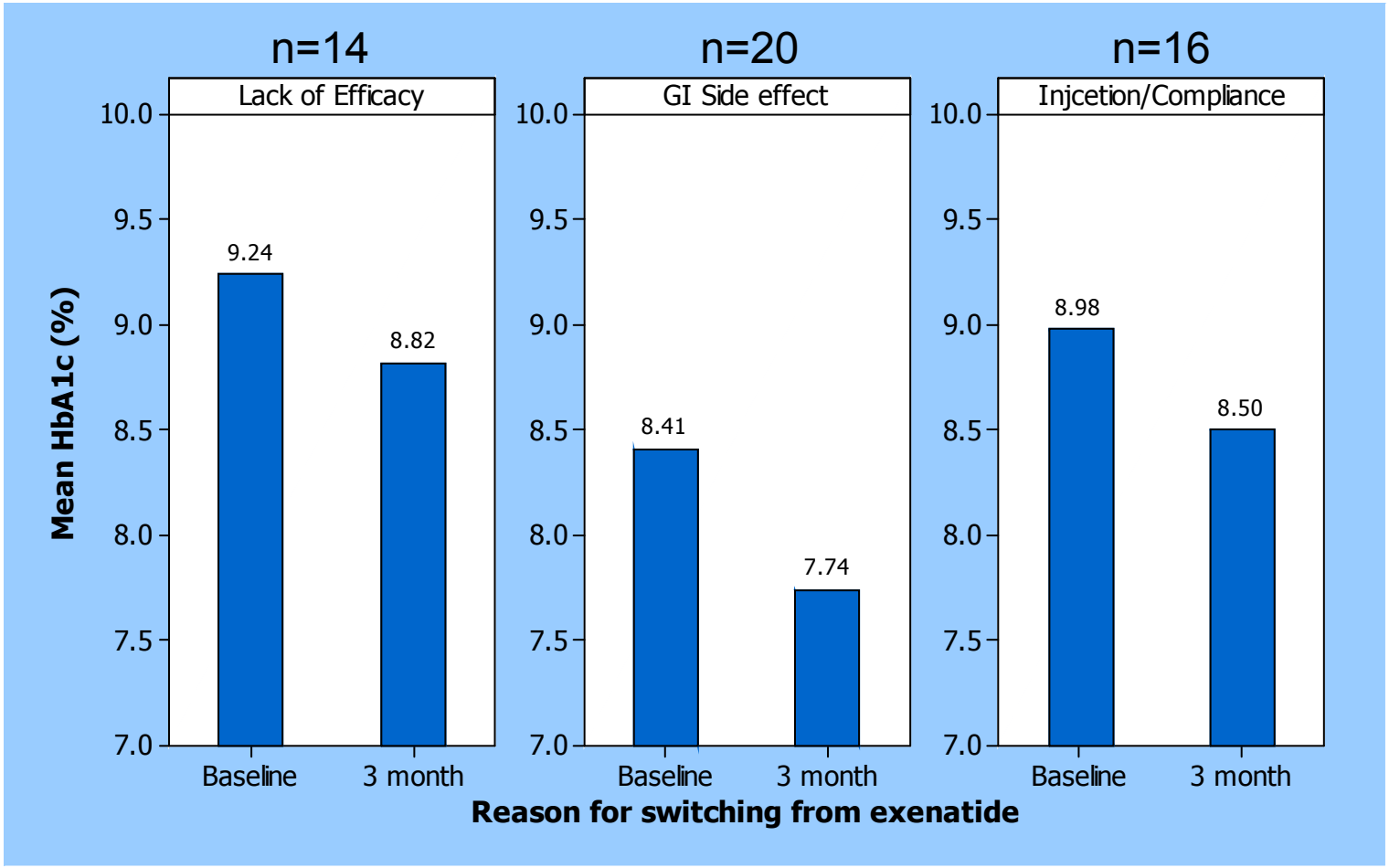
Baseline vs 3 month Weight among patients on Exenatide, DPPIV inhibitors and non-incretin therapies starting liraglutide



Mean change **-1.2 kg** P<0.001 **-2.8 kg** P<0.001 **-3.1 kg** P<0.001

Differences depending on reason for switch - HbA_{1c}



-0.42% -0.67% -0.48%

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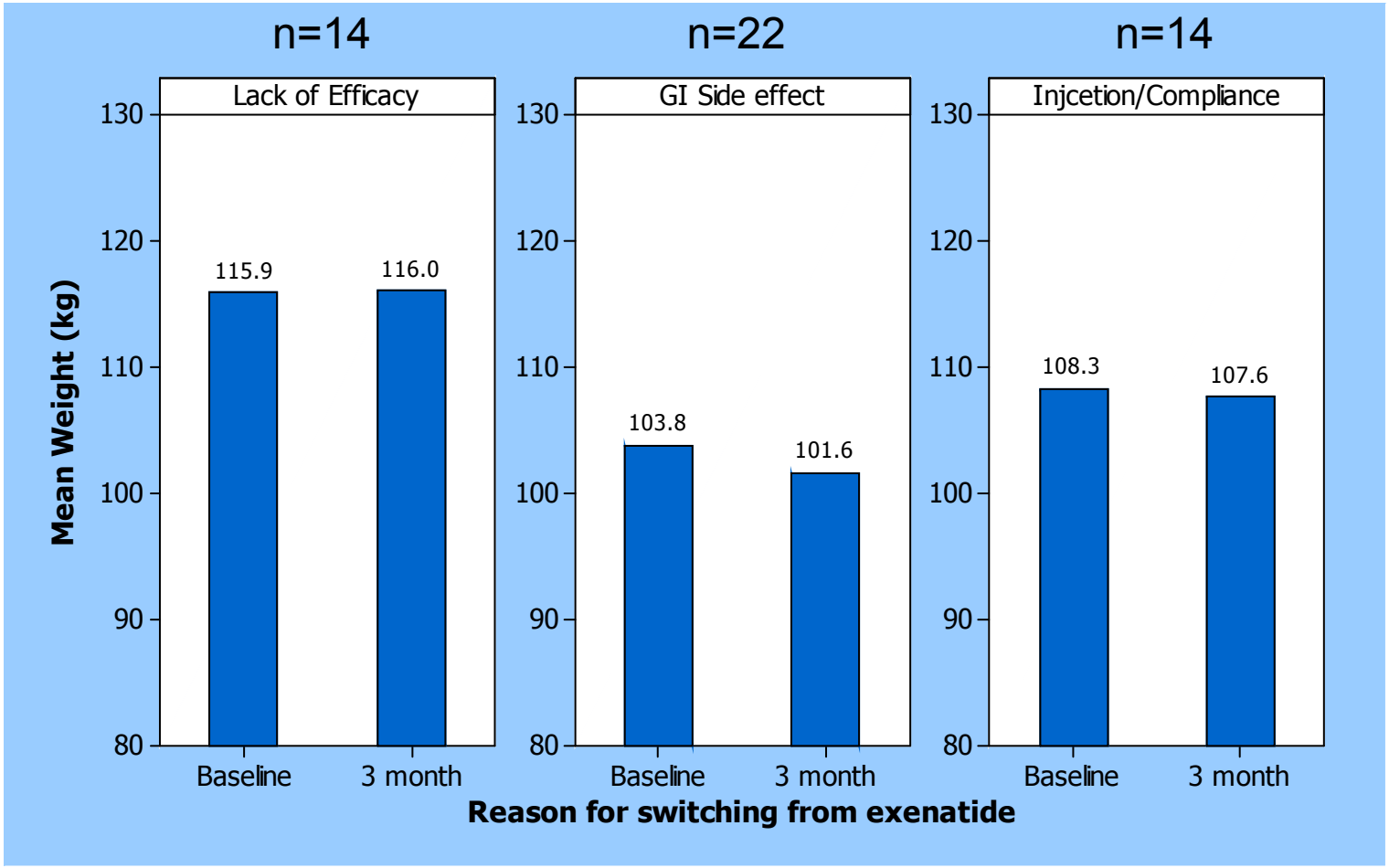
Differences depending on reason for switch - weight



+0.2 kg, p=0.826 -2.1 kg, p=0.001 -0.8 kg, p=0.478

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Patients switching from exenatide to liraglutide

- Patients switching from exenatide to liraglutide achieved less HbA_{1c} and weight reduction than patients not previously on incretin-based therapy.
- In patients who experienced GI side effects on exenatide a switch to liraglutide was associated with a significant improvement in HbA_{1c} and weight

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1.2 mg vs 1.8 mg

- 1807 patients had a recorded liraglutide dose at the 1st follow-up visit (the remainder didn't enter dose or hasn't had 1st follow-up yet)
  - 0.6 mg 171/1807 (9.5%)
  - 1.2 mg 1495/1807 (82.7%)
  - 1.8 mg 141/1807 (7.8%)

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Baseline characteristics

	1.2 mg (n=1495)	1.8 mg (n=141)	p value
Interval to 1st Follow-up (weeks)	14 (10-20)	16 (12-24)	0.038
Male (%)	55.2	56.7	0.719
Caucasian (%)	90.5	85.0	0.056
Age (yrs)	55.4 (11.1)	55.7 (11.0)	0.726
Diabetes duration (yrs)	9 (5-13)	10 (7-17)	0.004
HbA_{1c} (%)	9.20 (1.72)	9.83 (1.73)	<0.001
Weight (kg)	110.9 (22.8)	113.8 (23.8)	0.183
BMI (kg/m^2)	39.0 (7.6)	39.5 (7.3)	0.462
Previous Exenatide use (%)	21.5	29.8	0.024
On insulin (%)	40.1	48.9	0.041

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

Combination therapy of GLP-1 RAs and insulin is currently not licensed

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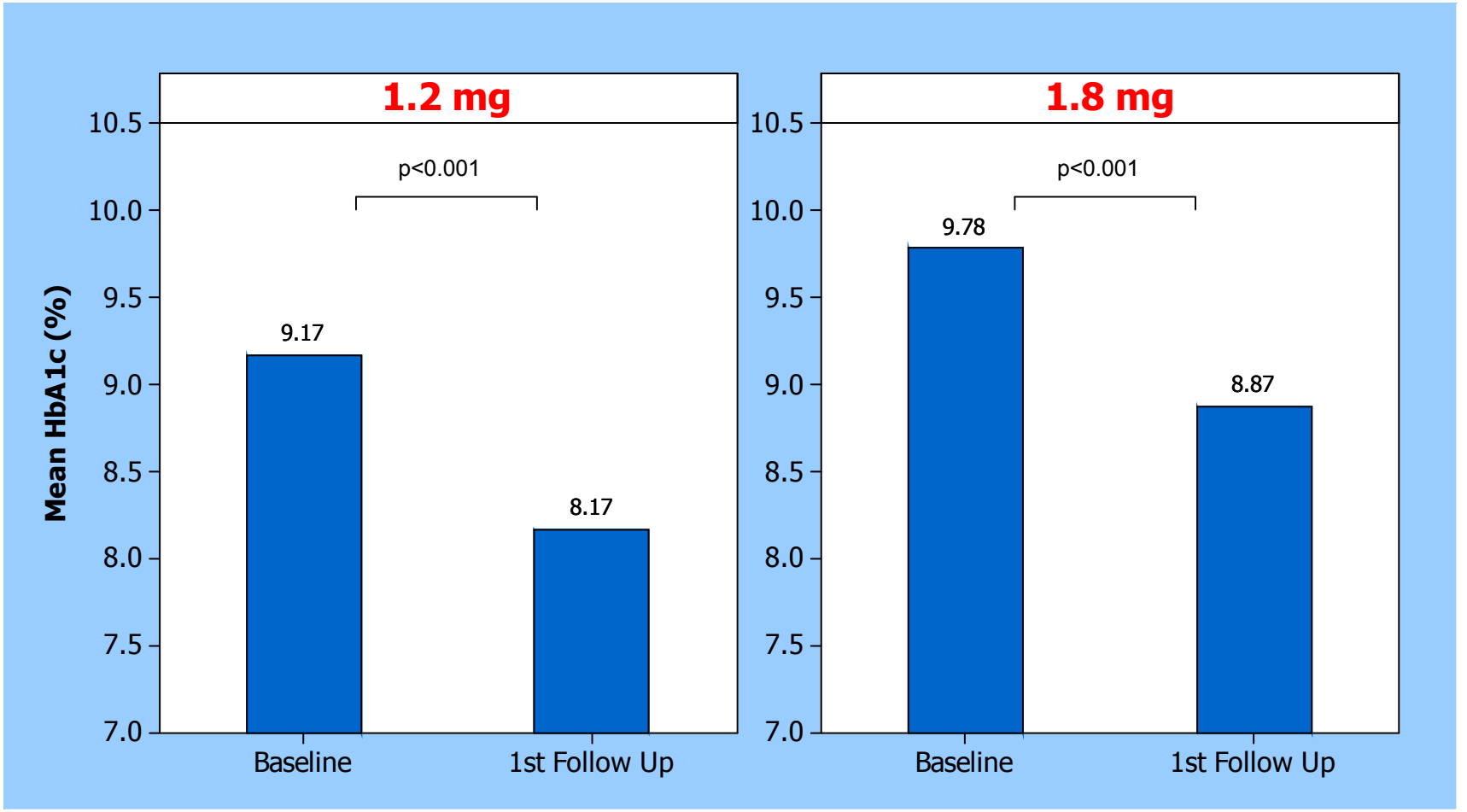
HbA_{1c} outcomes at first follow-up visit: 1.2 mg vs 1.8 mg



Median 16 (6-82) weeks

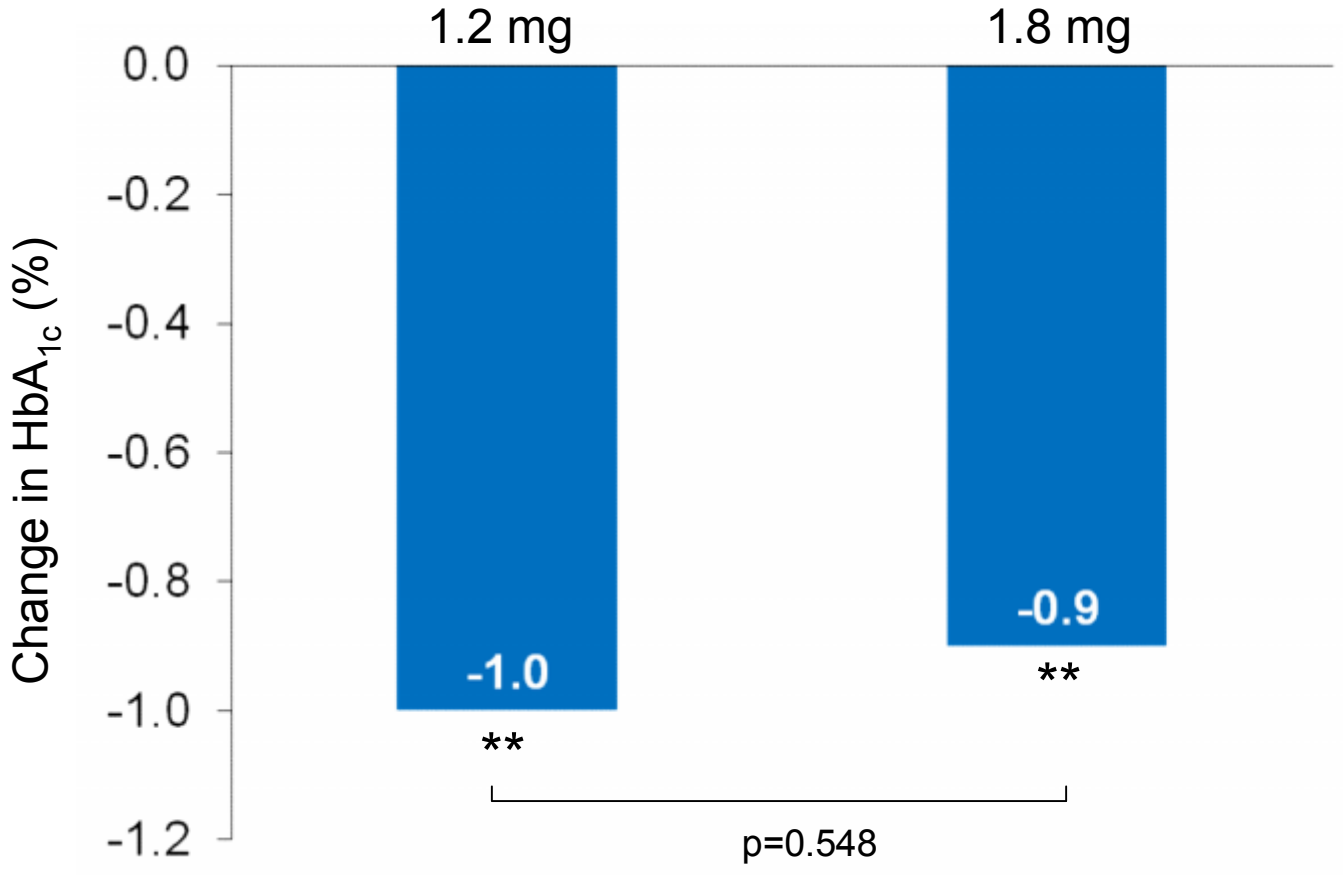
-1.00%

Median 16 (6-54) weeks

-0.90%

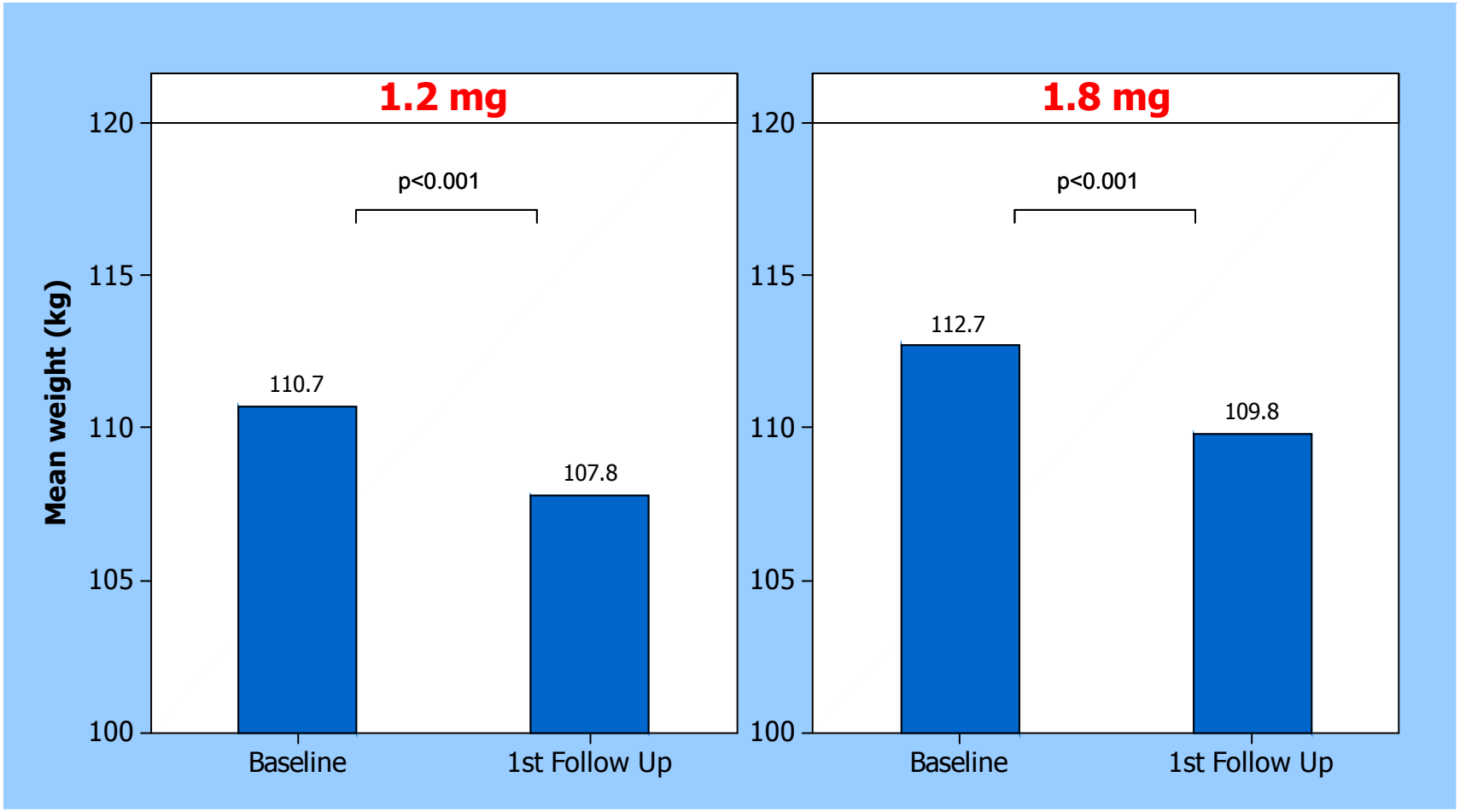
p=0.548

HbA_{1c} outcomes at first follow-up visit: 1.2 mg vs 1.8 mg



**p<0.001 compared to baseline

Weight outcomes at first follow-up visit: 1.2 mg vs 1.8 mg



Median 16 (6-82) weeks

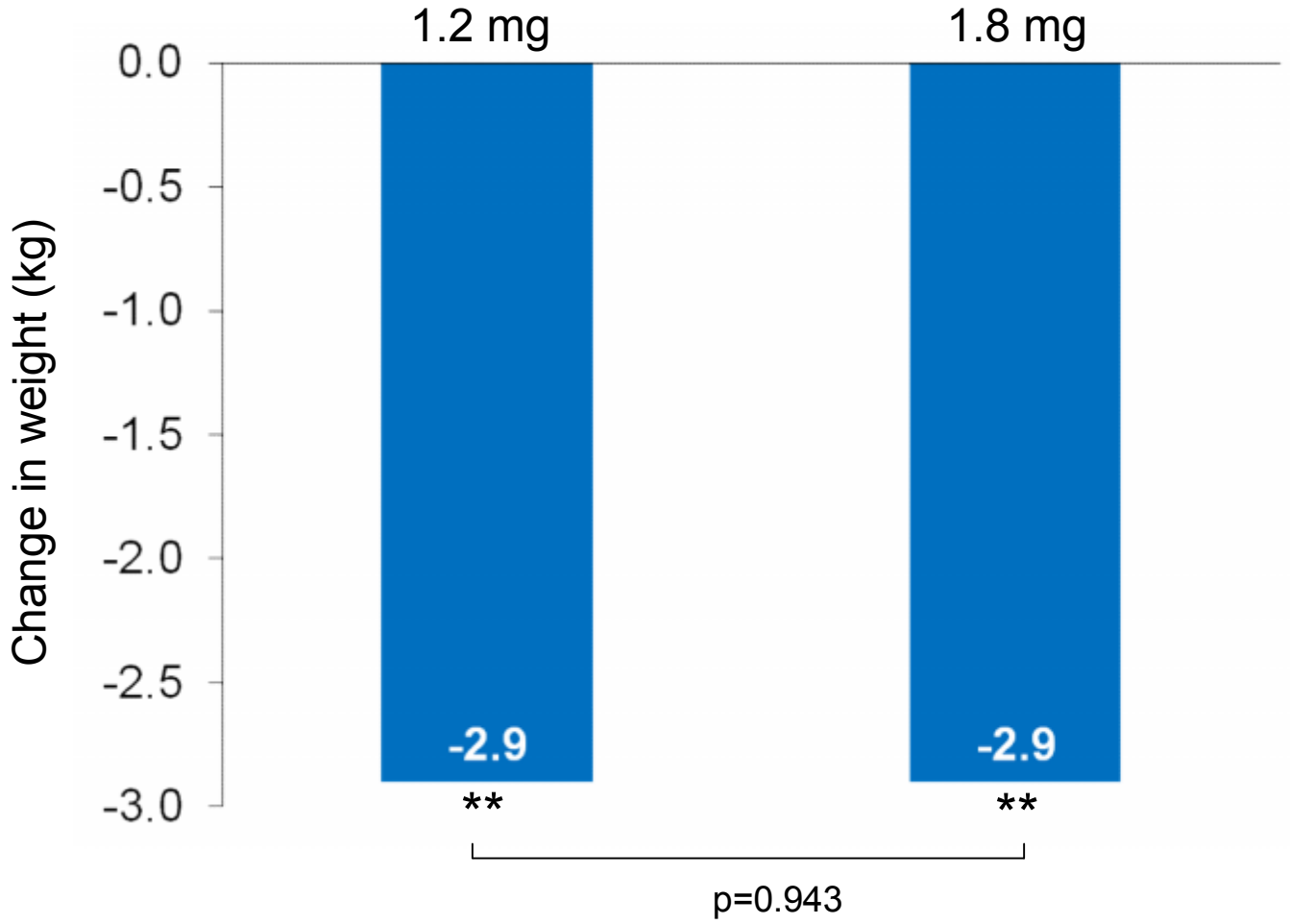
-2.9 kg

Median 16 (6-54) weeks

-2.9 kg

p=0.943

Weight outcomes at first follow-up visit: 1.2 mg vs 1.8 mg



**p<0.001 compared to baseline

Summary

- Liraglutide in routine UK practice appeared clinically effective
- ‘Switching’ from alternative incretin based therapies to liraglutide resulted in clinical benefit
- Similar efficacy for 1.2 mg and 1.8 mg doses, although patient phenotype significantly different
- Further data and analysis awaited.....

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ABCD nationwide exenatide audit contributors
The following are those whom we know about.

ABCD nationwide exenatide audit project steering group: *Ryder REJ, Walton C, Rowles S, Adamson K, Dove D, Thozhukat S*

ABCD nationwide exenatide audit – initial setup, maintenance and nationwide analysis: *Ryder REJ, Walton C, Winocour P, Cull ML, Jose B, Sukumar N, Mills AP, Sands K, Shafiq W, Rigby A, Thozhukat S, Thong K. Statistician: Blann A.*

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ABCD nationwide prospective liraglutide audit contributors

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