ABCD Nationwide Exenatide and Liraglutide Audits

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

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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 (Primary analysis completed)	Liraglutide (Recently started, *ongoing*)
Dates of data	2007-2009	*2009-2011*
Centres	126	*64*
Contributors	315	*210*
Patients	6717	*3010*
Duration of follow-up, median (range)	32 (0.1 – 175) weeks	*Ongoing*

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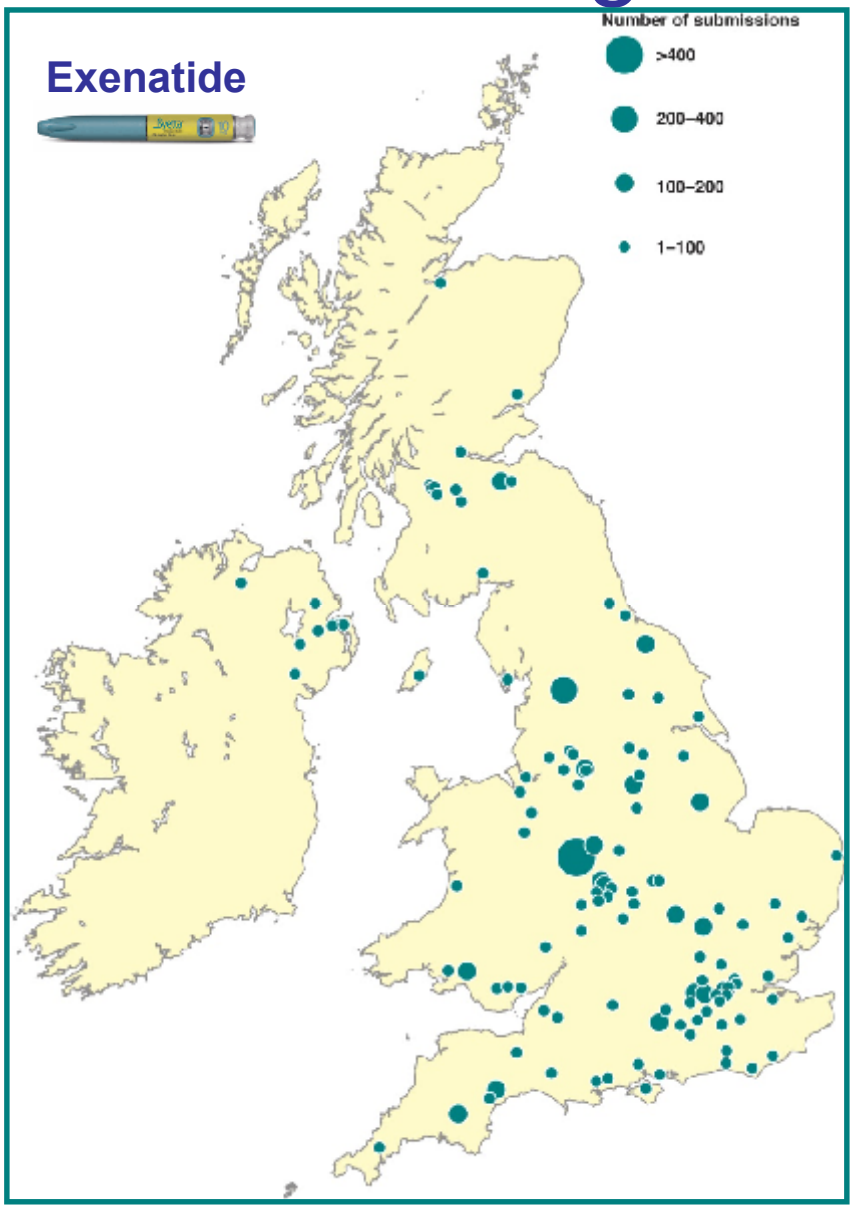
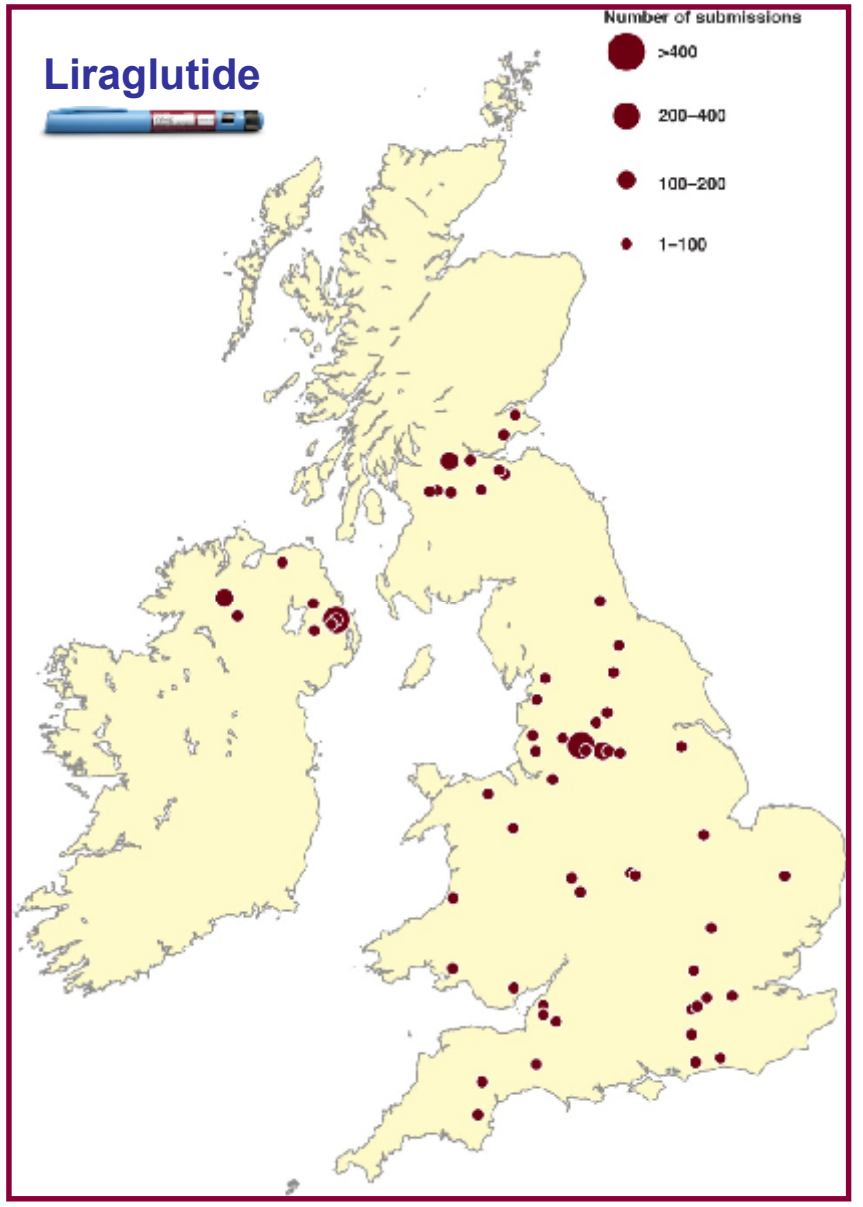
Nationwide contribution to exenatide and liraglutide national audit





Baseline characteristics

	Exenatide	Liraglutide
n	6717	*2303 (from 3010)*
Male (%)	54.9	*54.1*
Caucasian (%)	84.4	*90.4*
Age (yrs)	54.9 (10.6)	*55.4 (11.2)*
Diabetes duration (yrs)	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)

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

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Baseline characteristics – clinical trials versus clinical use

	Baseline HbA_{1c} (%)	Baseline BMI (kg/m^2)
Liraglutide clinical trials combined	8.5	31
Liraglutide real clinical use (ABCD audit)	9.5	39

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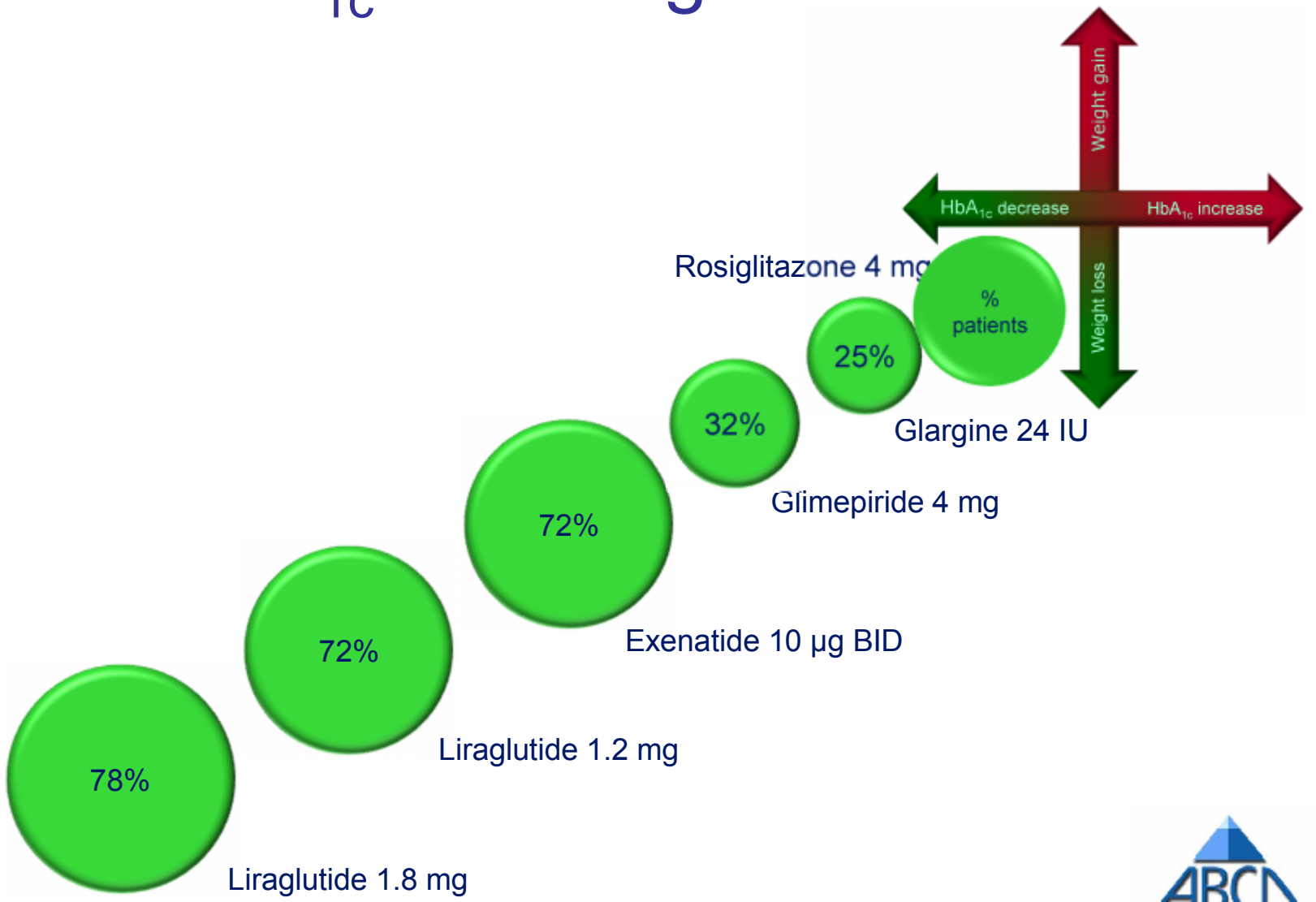
HbA_{1c} AND WEIGHT CHANGES

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



Data on file, Novo Nordisk

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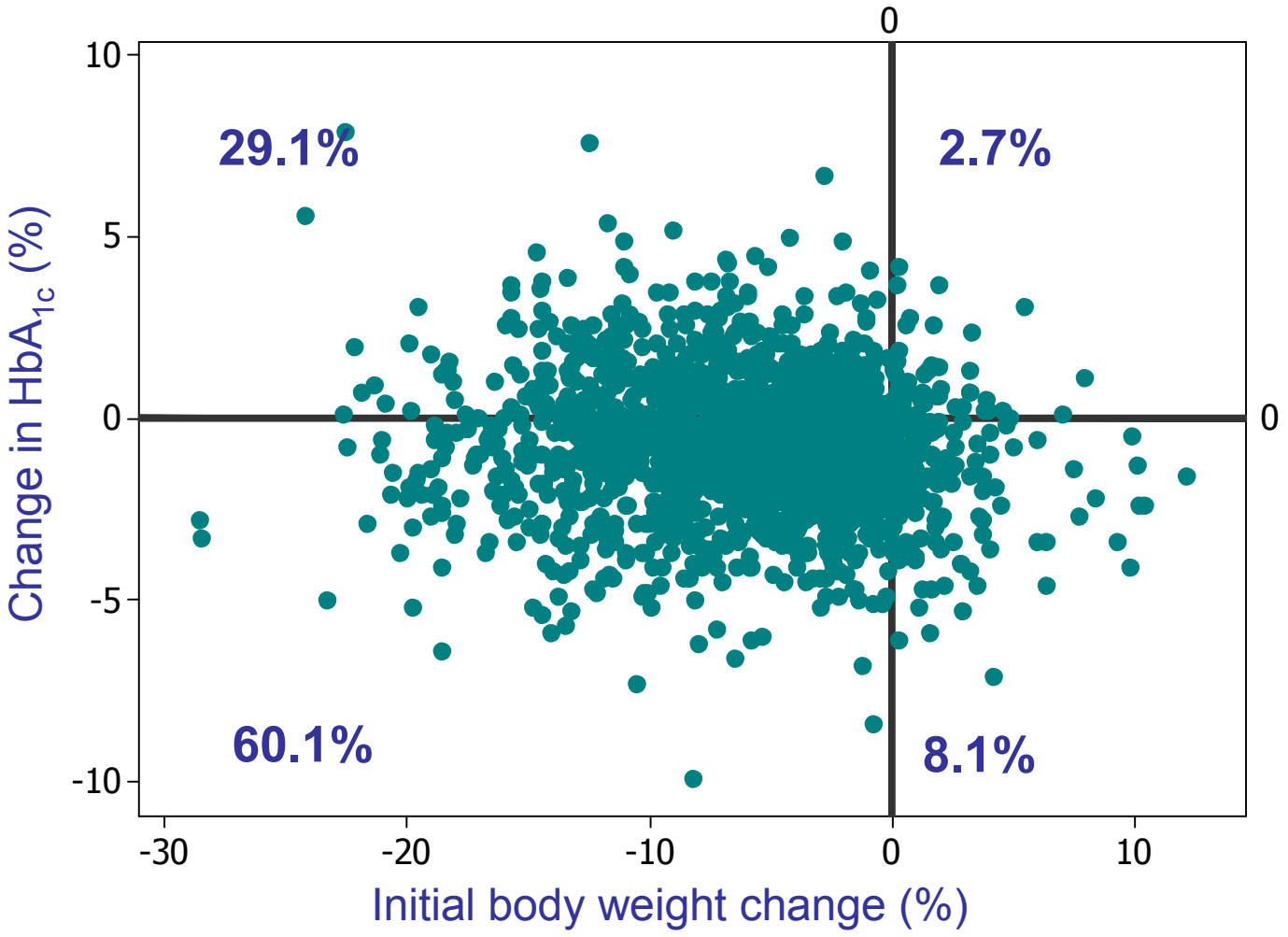
HbA_{1c} and weight changes at 6 months in 1882 patients on exenatide



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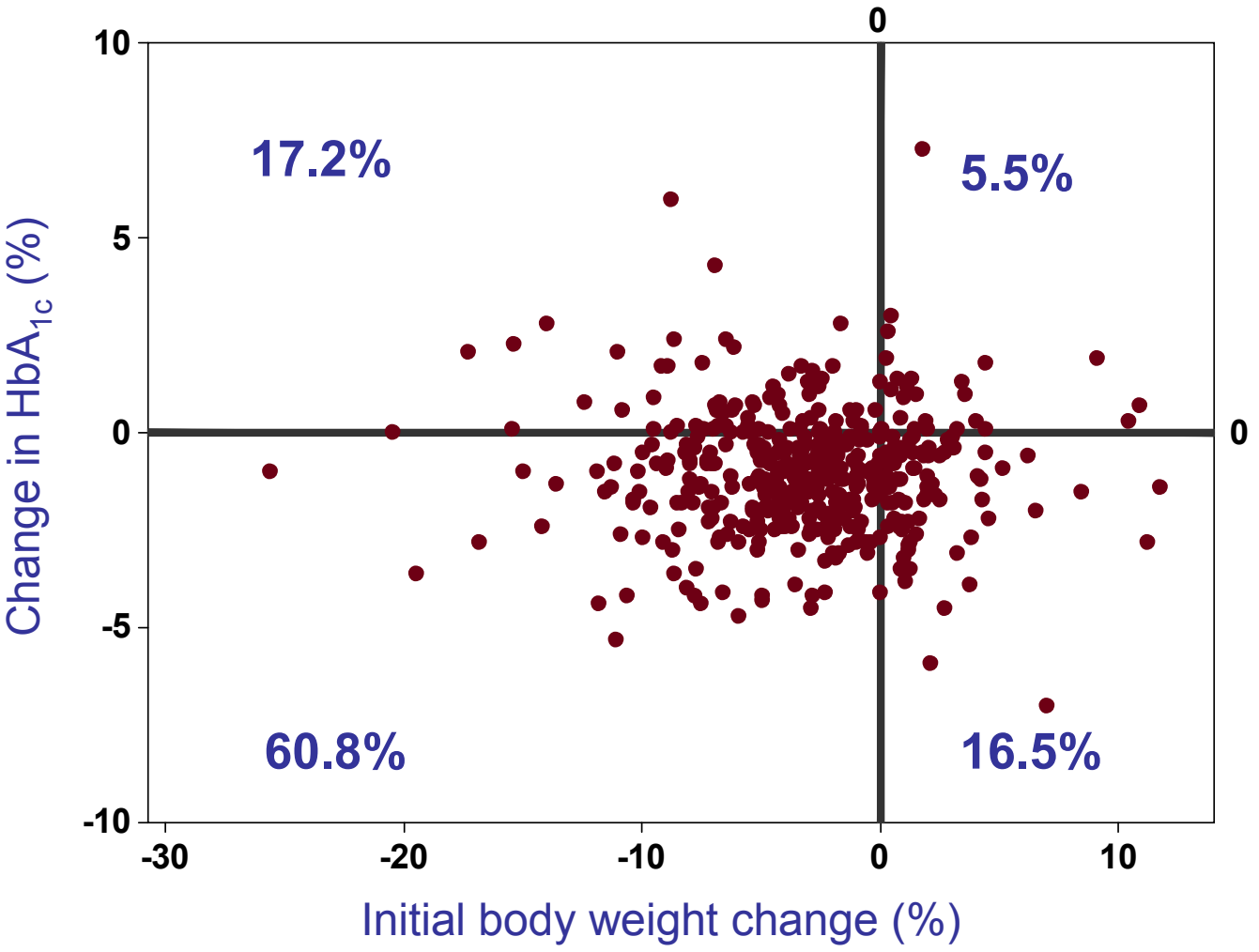
HbA_{1C} and weight changes at 6 months in 436 patients on liraglutide



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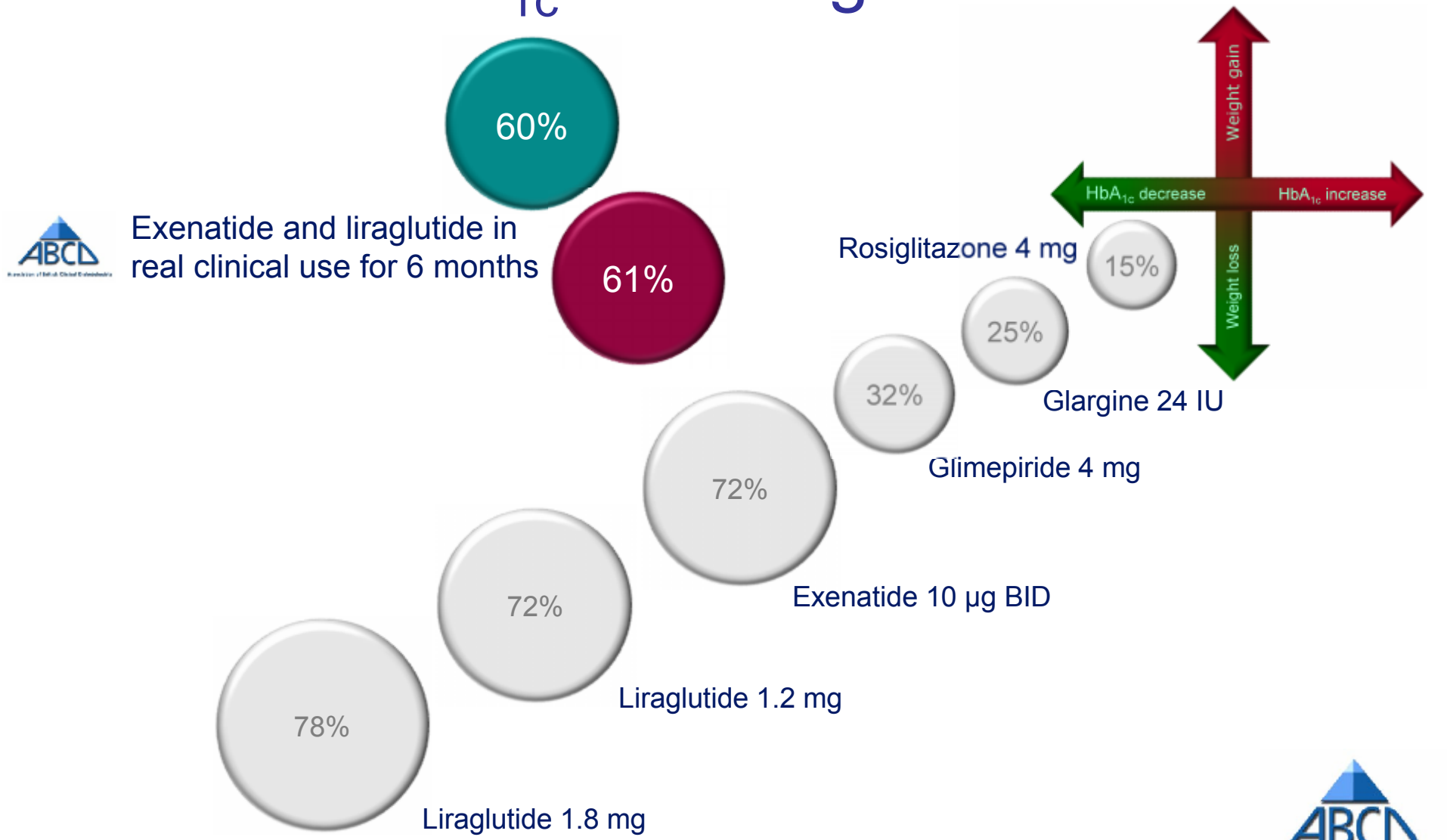
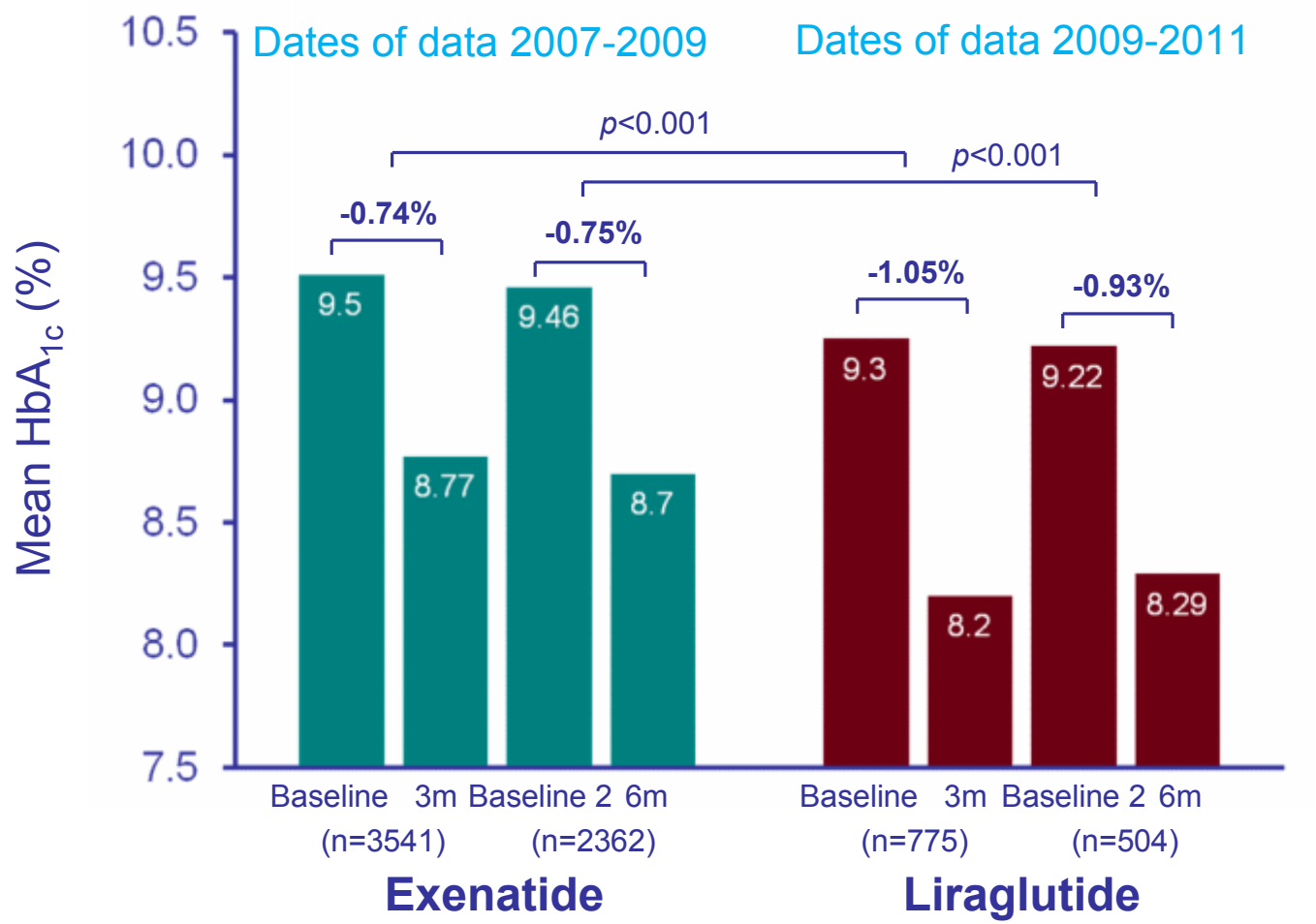
Percentage of subjects achieving fall in HbA_{1c} and weight loss

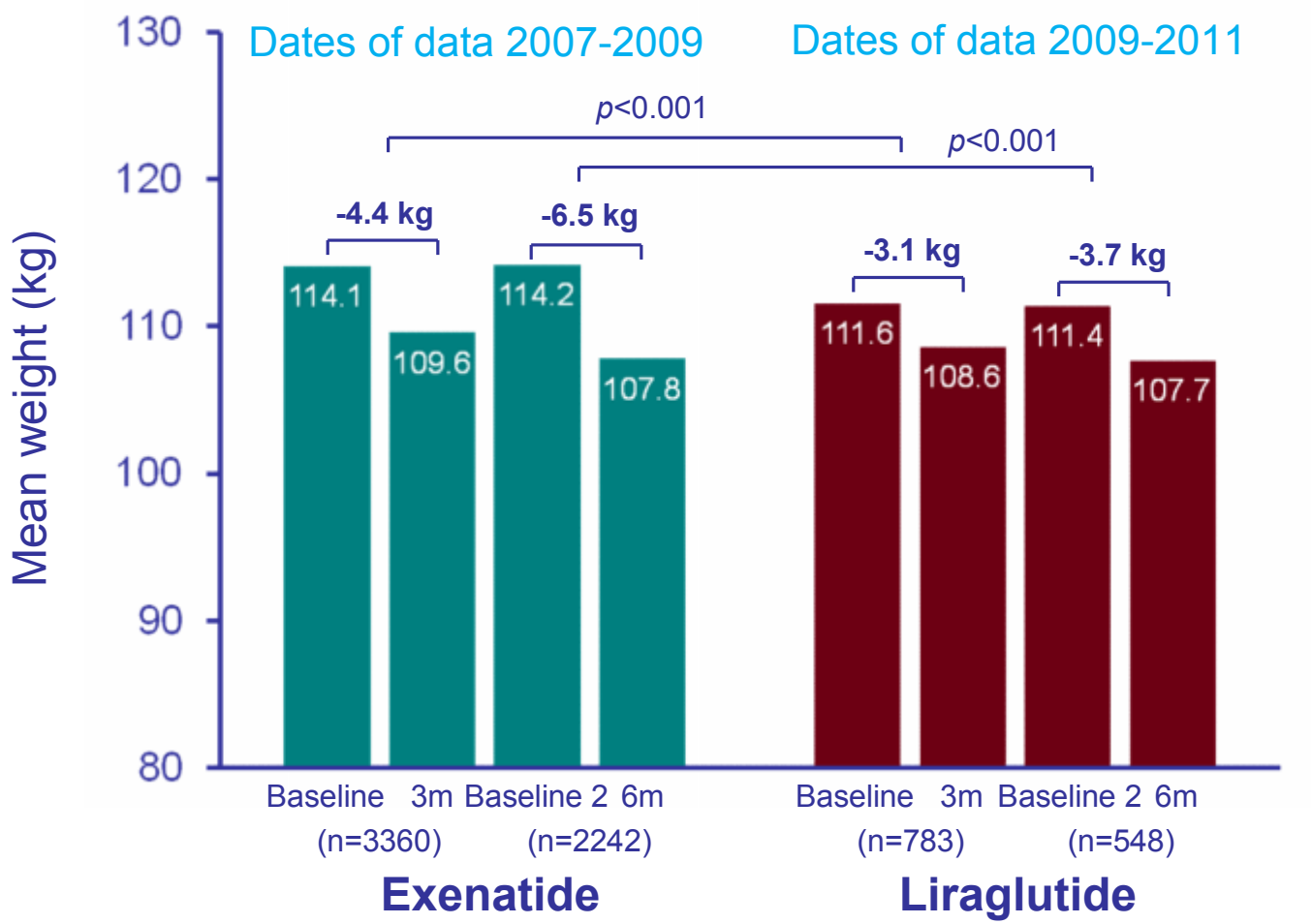


Data on file, Novo Nordisk

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

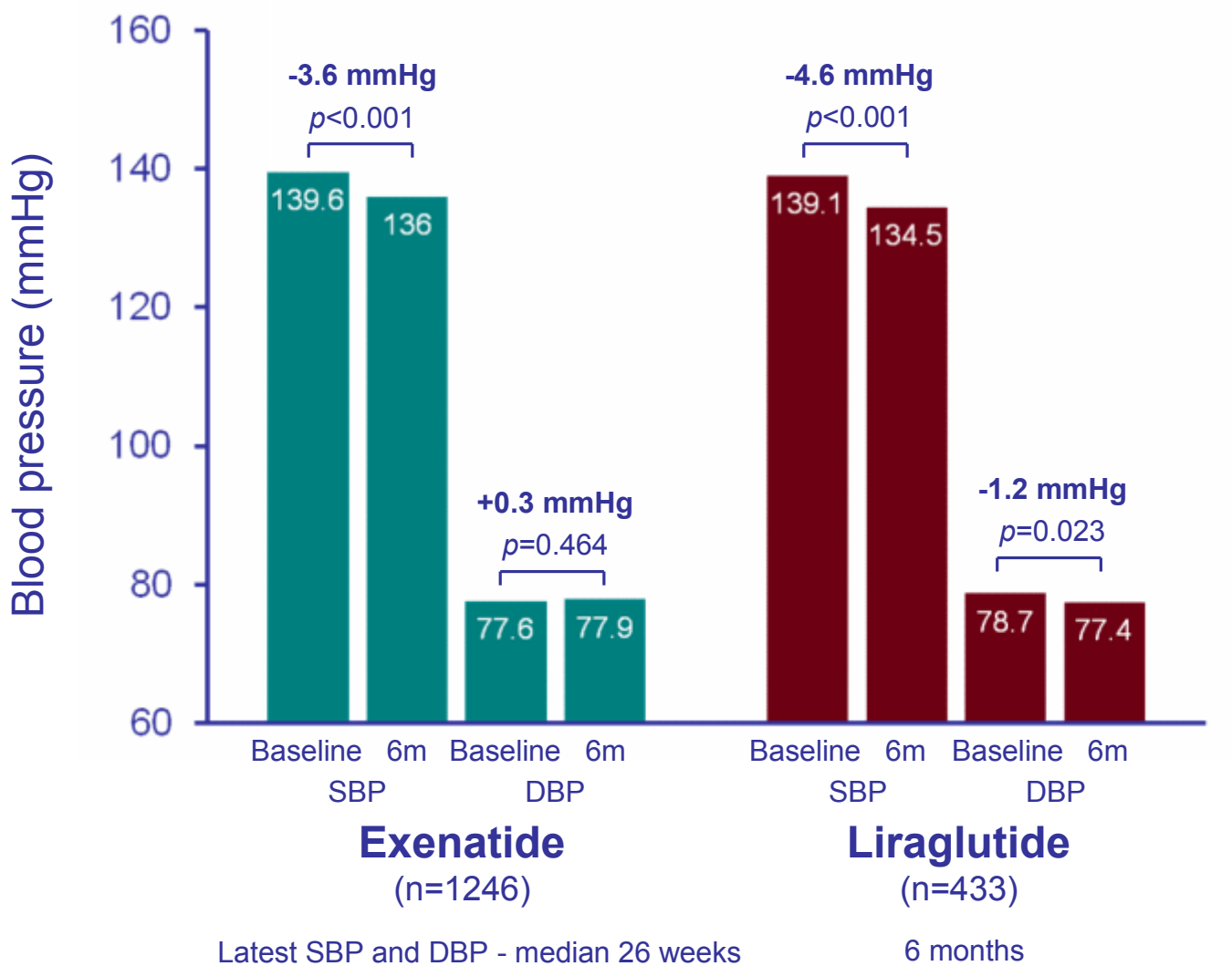


Weight results at 3 and 6 months: exenatide and liraglutide



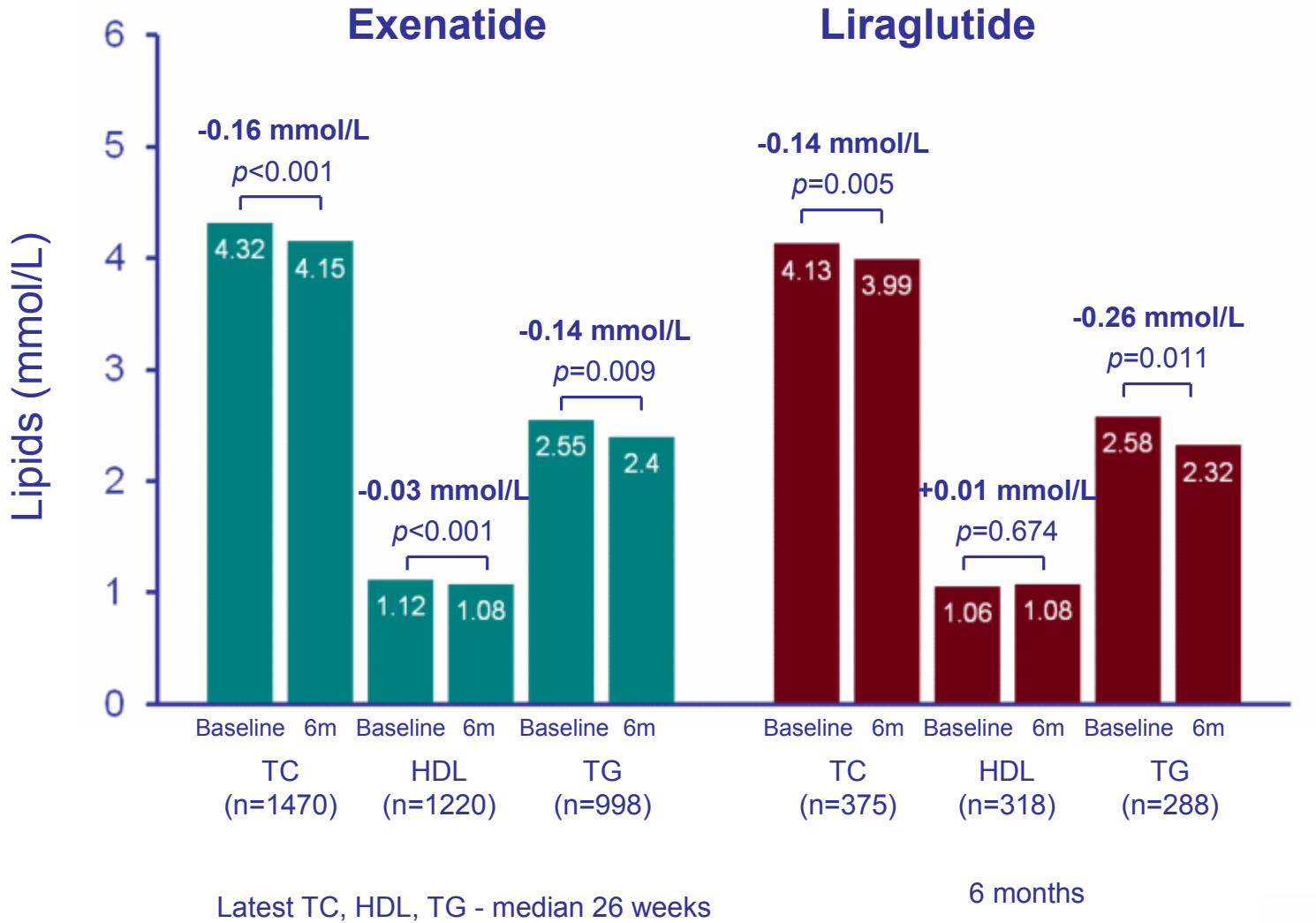
BLOOD PRESSURE AND LIPIDS

Changes in blood pressure



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

Changes in lipid profiles



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

Summary of adverse events

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	3.3% (pre) / 5.6% (post)	*1.0% (post)*	
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	*3 hypothyroidism, 1 hyperthyroidism, 1 benign thyroid adenoma*	
Bleeding	Not ascertained	*2 epistaxis, 1 GI, 1 GU*	
Raised LFT	Not ascertained	*3 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
- Changing behaviour of clinicians

Baseline diabetes treatment use (and discontinuation)

	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)*

As a percentage of 6717 and 3010 patients respectively

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

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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
  - 707/3010 (23.5%)
- Switch from DPP-4 inhibitor
  - 271/3010 (9.0%)
- Switch from oral non-incretin
  - 286/3010 (9.5%)

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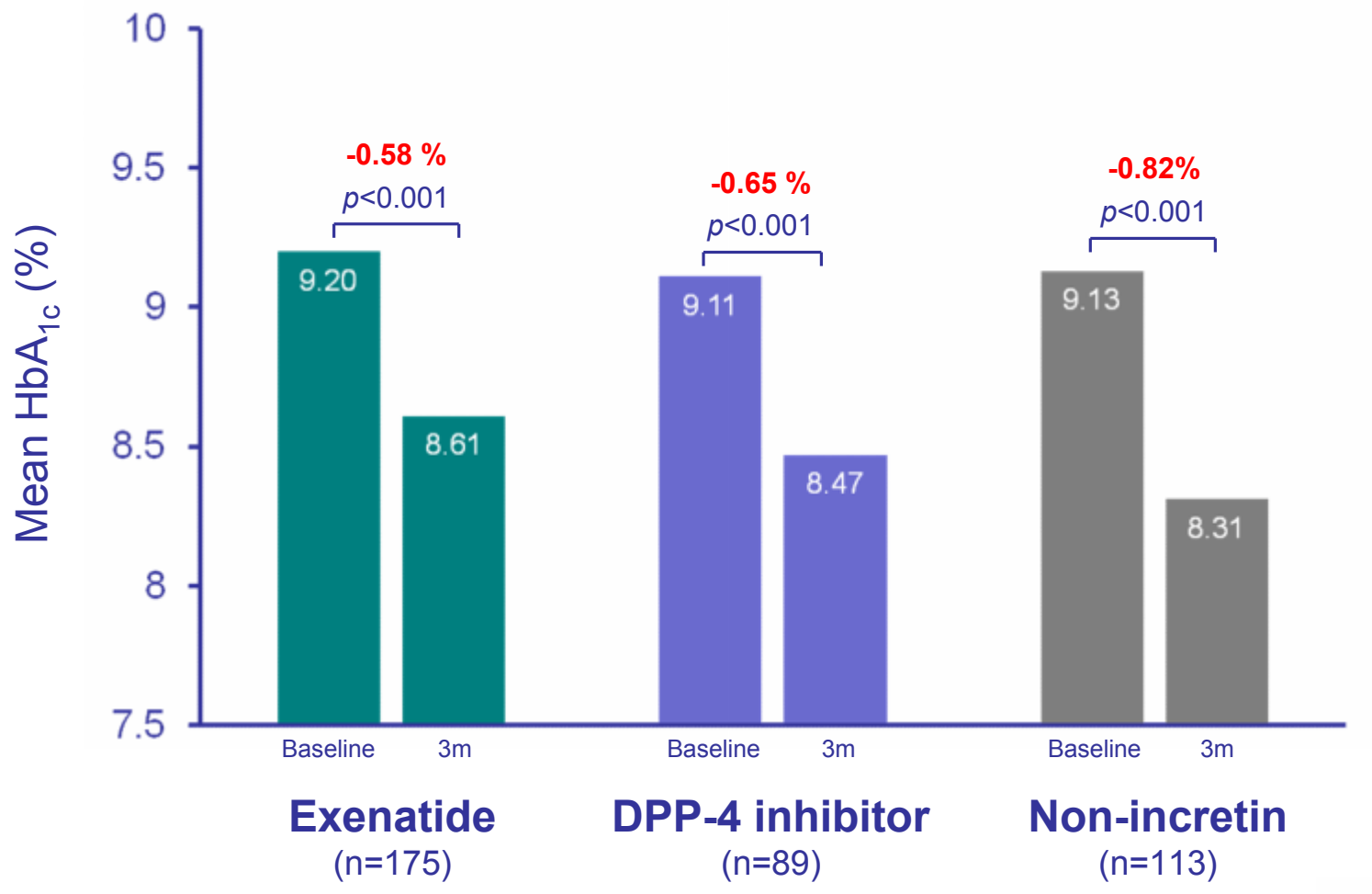
Switching from exenatide, DPP-4 inhibitor or oral non-incretin drug to liraglutide: Baseline vs. 3 month HbA_{1c} data



ANOVA three groups, *p*=0.409

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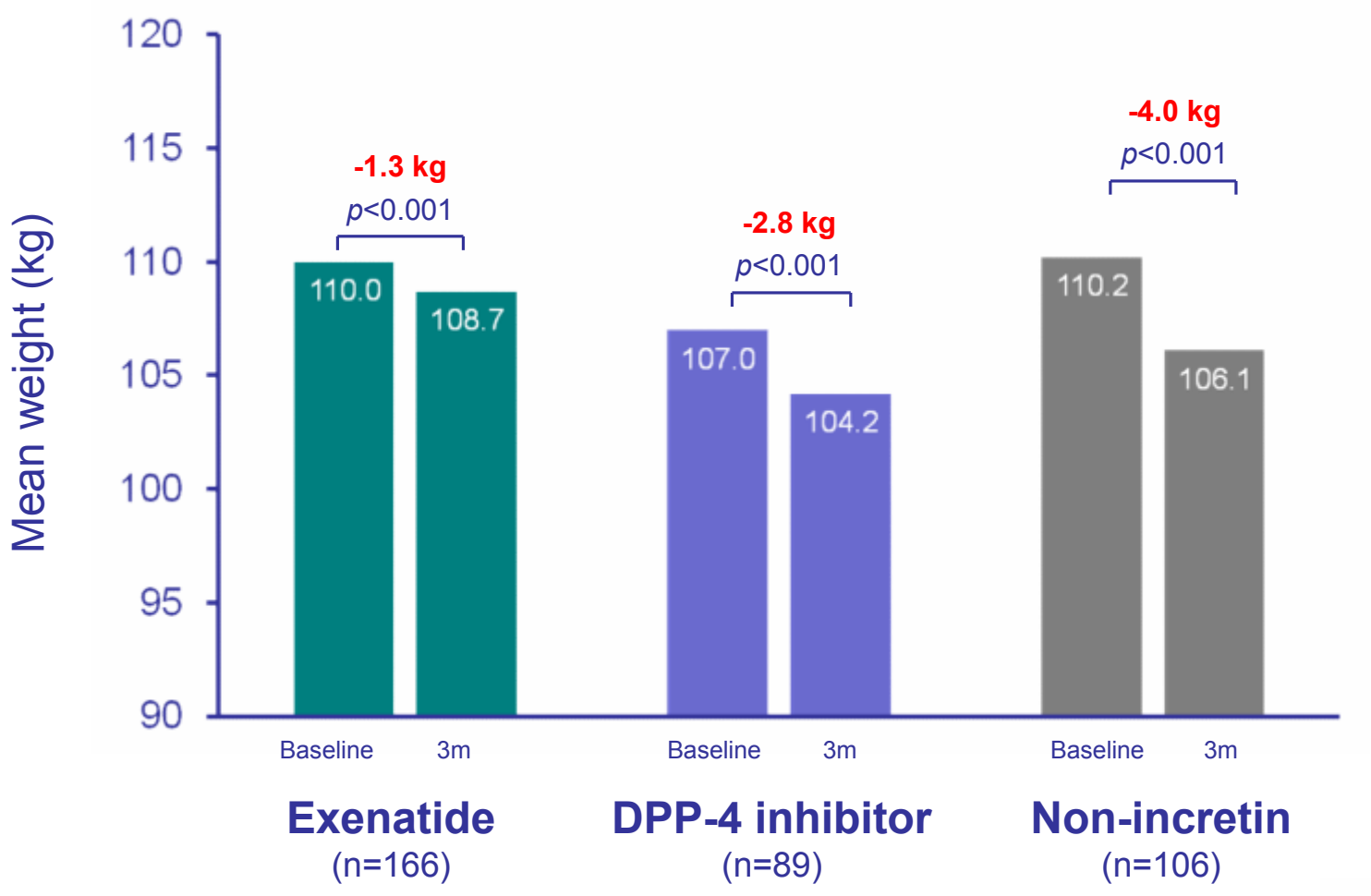
Switching from exenatide, DPP-4 inhibitor or oral non-incretin drug to liraglutide: Baseline vs. 3 month weight data



ANOVA three groups, $p<0.001$ (exenatide vs non-incretin switch $p<0.001$; exenatide vs DPP-4 inhibitor switch $p<0.05$)

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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

1807 patients had a recorded liraglutide dose at the 1st follow-up visit

- Liraglutide 0.6 mg 171/1807 (9.5%)
- Liraglutide 1.2 mg 1495/1807 (82.7%)
- Liraglutide 1.8 mg 141/1807 (7.8%)

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Baseline characteristics of liraglutide 1.2 mg and 1.8 mg

	Liraglutide 1.2 mg (n=1495)	Liraglutide 1.8 mg (n=141)	*p*-value
Male (%)	55.2	56.7	NS
Caucasian (%)	90.5	85.0	NS
Age (yrs)	55.4 (11.1)	55.7 (11.0)	NS
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)	NS
BMI (kg/m^2)	39.0 (7.6)	39.5 (7.3)	NS
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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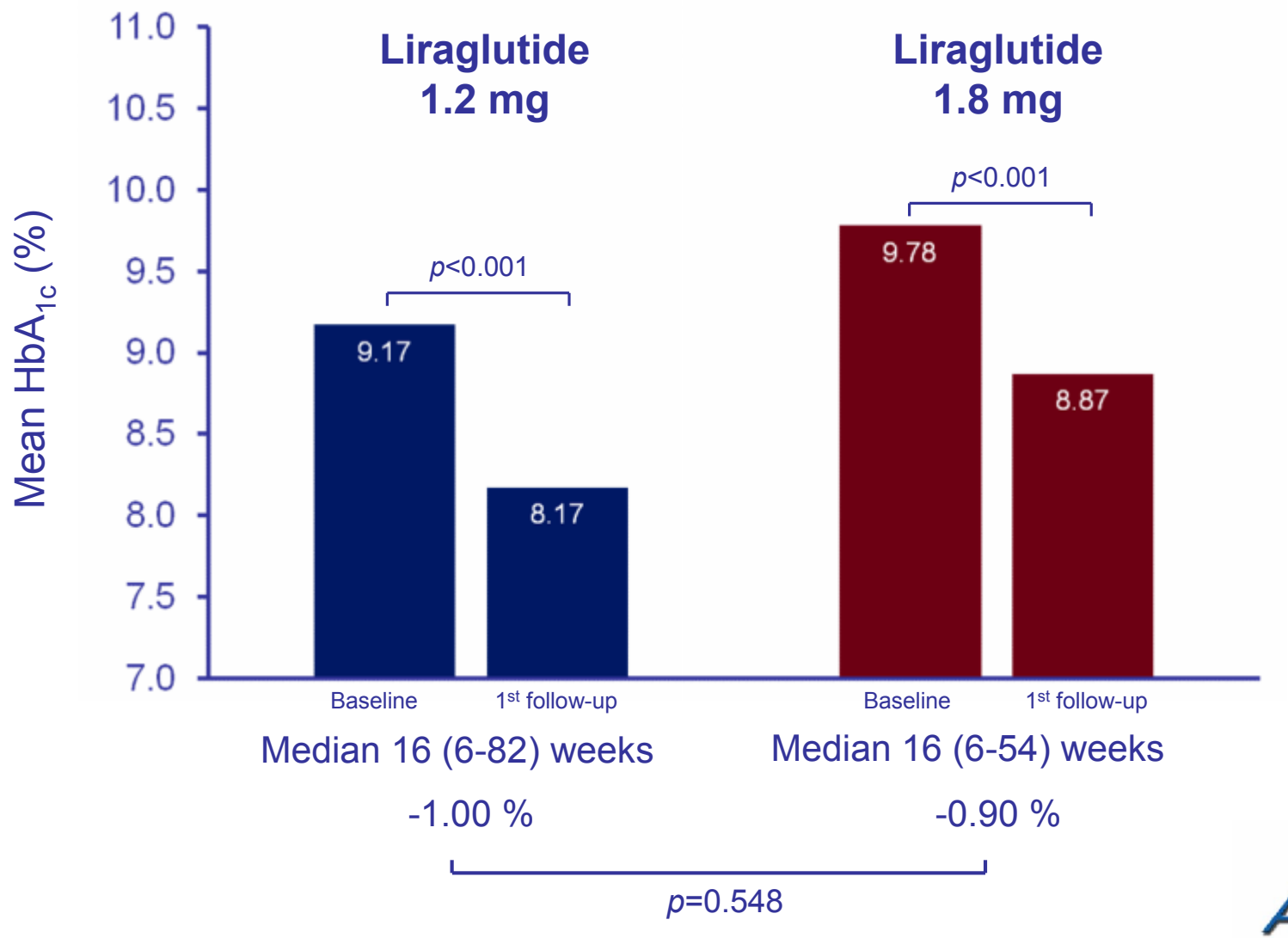
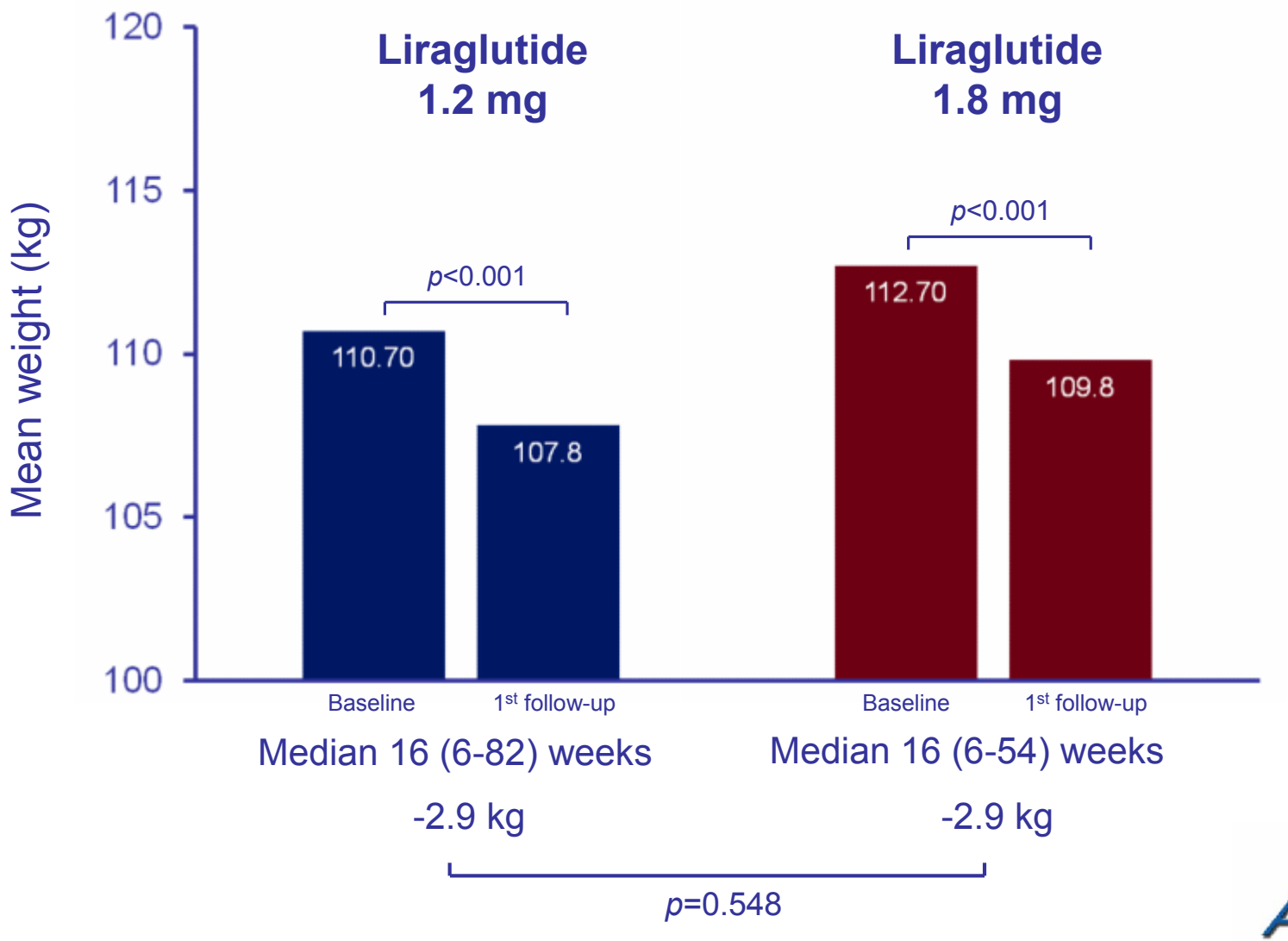
HbA_{1c} outcomes at first follow-up visit: 1.2 mg vs 1.8 mg



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



Summary

- ABCD national audits provides real life data for GLP-1 based therapies in T2DM
- Patients are much heavier and more poorly controlled than in clinical trials
  - Changes in HbA_{1c}, weight, blood presure and lipids reflect those seen in RCTs
- Differences observed between exenatide and liraglutide likely reflect differences in cohorts and experience of GLP-1 receptor agonist use
- HbA_{1c} and weight benefits of switching from other incretin-based therapies to liraglutide in appropriate patients
- Use by clinicians outside prescribing guidelines

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

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Addenbrookes Hospital: Simmons D, Bejinariu E. **Altnagelvin Area Hospital:** Lindsay J, O'Kane M, Black N, Moles K, Williams L, Caskey H, McDaid A-M, King L, McIlvor E, Hamilton L, Early R, Morahan S, Giff K, Johnston S. **Basildon University Hospital:** Mulcahy M, Krishnan L. **Belfast City Hospital:** Henry RW, Nugent A, McMullan P. **Benhsam General Hospital:** Narayanan KR. **Birmingham Community Healthcare NHS Trust:** Muralidhara K, Shahid S, Thomas A, Cunningham B, Haughton K. **Bristol General Hospital:** Croxson S. **Bristol Royal Infirmary:** Richards G, Pople J-A, John H, Jones L. **Bronglais Hospital:** Kotonya C, Phillips L, Saunders H, Powell P. **Cape Hill Medical Centre (GP):** Gardner G, Chitnis J, Merali A, Maan P. **Causeway Hospital:** Kassim SB, Ryan MF, Diong KL, Hutchinson K, Glass M, Spiers K, Woodend J, Davidson E. **Chorley Hospital:** Rajbhandari SM, Acharya S. Whittaker J, Caunce K. **City Hospital, Birmingham:** Ryder REJ, Basu A, De P, Lee BC, Thong KY, Blann A, Mills AP, Cull ML, Burbridge W, Irwin S, Cutler J, Zzizinger A, Mehrali T, Guthrie S, Bedi T, Stevenson-Mort J. **Dewsbury Hospital:** Bissell J. **East Lancashire Hospital NHS Trust:** Ramtoola S, Ali A, Jones G, Wilkinson R, Littley M, Mishra M, Glew M, Jostel A, Demssie Y. **East Surrey Hospital, Redhill:** Sennik D, Prajapati C, Chinnasamy E. **Forth Valley Hospital:** Buchanan L, Mackintosh L. **Friarage Hospital, Northallerton:** Owen K, Kamaruddin MS, Leek C. **Furness General Hospital:** Banerjee M, Obale O. **Huddersfield Royal Infirmary:** Moisey R. **Hull Royal Infirmary:** Sugunendran S, Sathyapalan T, Walton C. **King's College Hospital, London:** Vitello S, Hunt K. **Lagan Valley Hospital, Lisburn:** Au S. **Leicester General Hospital:** Tarigopula G, Kong M-F, Gregory R, Jackson S. **Leicester Royal Infirmary:** Htike ZZ. **Monklands Hospital, Airdrie:** Sandeep TC, White A. **New Cross Hospital, Wolverhampton:** Singh BM, Khalid Y, Nayak AU, Katreddy V. **Newham University Hospital, London:** Gelding S, Menon R, Balakumar Y. **Ninewells, Dundee:** George P. **North Tees & Hartlepool Trust:** Robinson M, Dobson M, Presgrave M, Mehaffy J, Roper N, Pye S, Macleod J, Worrall E, Sinclair J, Anthony S, Jones S. **Pendyffryn Medical Group (GP):** Morrison CL. **Pennine Acute Hospitals Trust:** Smith G. **Pilgrim Hospital, Boston:** Jacob K, Htwe N. **Pinderfields General, Wakefield:** D'Costa R. **Pontefract General Infirmary:** Bissell J. **Queen Elizabeth II Hospital & Lister Hospital, Welwyn Garden City:** Winocour PH, Darzy K, Qureshi SA, Ford M, Barker L, O' Donnell L. **Royal Blackburn Hospital:** Ramtoola S, Ali A, Jones G, Wilkinson R, Littley M, Mishra M, Glew M, Jostel A, Demssie Y. **Royal Devon & Exeter:** Lockett H. **Royal Infirmary of Edinburgh:** McLaren J. **Royal United Hospitals, Bath:** Allen K, Higgs E, Robinson A, Ward A, Ward A, Hall B, Hillier N, Catchpole S, Wylie S. **Royal Sussex County Hospital, Brighton:** Burberry A. **Royal Victoria Hospital, Belfast:** Cooke B, Hunter S, Mcerlean U. **Sandwell Hospital, West Bromwich:** Davies P, Rock K. **Singleton Hospital, Swansea:** Udiawar M. **Smethwick Health Centre:** Harrington J. **Southern General Hospital, Glasgow:** Semple C, Struthers S, Kennon B. **St George's Hoapital, London:** Ahmed FW, Bano G, Patel N, Flanagan A, Wilson Z, O'Brien J, Firth P. **St John's Hospital, Livingston:** Teoh WL, Adamson K. **St Stephens Gate Medical Practice (Norfolk PCT) (SSGMP):** Haylock C. **Stirling Royal Infirmary:** Kelly C, Mackenzie A, Ryan L, Dewar L. **Stobhill Hopsital:** Smith C, Gordon D. **Sunderland Royal:** Nayar R, Carey P, Aspray T. **Torbay Hospital, Torquay:** Paisey R, Smith J, Lissett K, Dyer R, Dimitropoulos I, Weekes C. **Trafford General Hospital:** Snell A, Stephens WP, George A, Hopewell L. **Tyrone County Hospital:** Helmy A, Hameed A, McGirr B, Patterson H, Monaghan S, Bradley P, Evan H. **Ulster Hospital, Belfast:** Harper R, Carr S, McDonald P, Harding J, McIlwaine W, McLaughlin D, Whitehead H. **Victoria Hospital, Kirkcaldy:** Duncan C, Chalmers J. **Western General Hospital, Edinburgh:** Zammitt N. **Westmoreland General Hosptital:** Banerjee M, Obale O. **Wharfedale Hospital:** Amery C. **Wrexham Maelor:** Dixon AN. **Yeovil District Hospital:** Bickerton AST, Pramodh S, Crocker M.

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