

ABCD Nationwide Exenatide Audit

Dr Bob Ryder on behalf of the ABCD nationwide exenatide audit contributors:

ABCD Spring meeting, Bristol, May 8, 2009

ABCD nationwide exenatide audit contributors

The following are those whom we know about who contributed the 3913 patients who are the subject of this presentation. The full audit, which is ongoing, has many other contributors who will be listed in future presentations which will include their patients

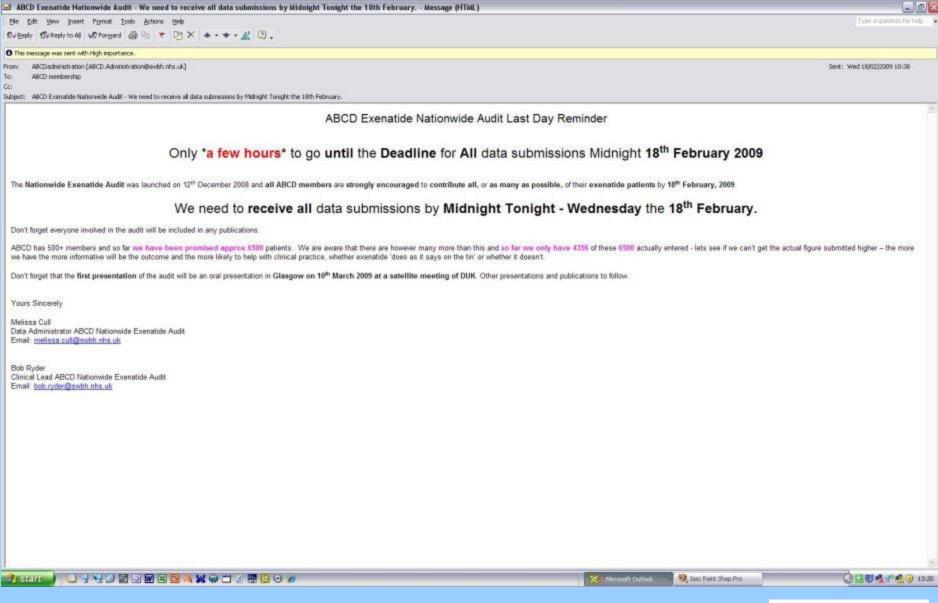
ABCD nationwide exenatide audit – initial setup, maintenance and nationwide analysis: Ryder REJ, Walton C, Winocour P, Cull ML, Jose B, Sukumar N, Mills AP, Sands K. Statistical Advisor: Blann A.

Addenbrookes Hospital: Adler A, Evans M, Simmons D, O'Rahilly S, Coll T, Faroogi S, Park A. Barnsley Hospital: Uchegbu E. Basildon University Hospital: Mulcahy M, Krishnan L. Basingstoke and North Hampshire NHS Foundation Trust: Guy R, Turner B, Akester K, Lewis G, Harrison O, Tombling S, Lloyd G, Hughes C, Lowe C. Bedford Hospital: Morrish N, Melvin A, Pledger J, Barron R. Bedfordshire & Hertfordshire PGMS, Luton: Rehman T, Sinclair A. Belfast City Hospital: Henry W. Bolton Diabetes Centre: Palin S, Kenz S. Bristol Royal Infirmary: Raghavan R, Phillips S, Bradley K. Bronglais Hospital, Aberystwyth: Kotonya CA. Caerphilly Hospital: Premawardhana LDKE. Chesterfield Royal Hospital: Mohammad M, Robinson RTCE, MacInerney RM. Chorley & South Ribble Hospital: Rajbhandari SM, Acharya S. City Hospital, Birmingham: Ryder REJ, Basu A, De P, Lee BC, Jose B, Sukumar N, McAloon CJ, Blann A, Mills AP, Cull ML, Lee A, Rawcliffe C, Ryder B, Burbridge W, Irwin S, Cutler J, Zzizinger A, Mehrali T, Bedi T. CMMC Foundation Trust, Manchester: Jinadev P, Watts R, Abul-Ainine S, Salahuddin S. Colchester General Hospital: Bodmer C. Conquest Hospital, St Leonards on Sea: Dashora U, Castro E. Countess of Chester: Goenka N. County Hospital, Hereford: Lloyd J. Craigavon Area Hospital, Co Armagh: Ritchie C. Daisy Hill hospital, Newry: Adil MM. Derriford Hospital, Plymouth: English P. Dumfries & Galloway Royal Infirmary: Bell E. East Surrey Hospital, Redhill: Foster K, Natarajan G. Eastbourne District Diabetes Centre: Bending J, Afolayan J, Sheppard P. Fairfield Hospital, Bury: Rowles S, Smithurst HJ. Falkirk and District Royal Infirmary: Kelly C, Peden N, Currie J. Furness General, Barrow In Furness: Chuni P, Hay C, Narayan S, Krishnan S. Gartnavel General Hospital: McGrane D, Sainsbury C, Fisher. George Eliot, Nuneaton: Shaikh S. Good Hope Hospital, Sutton Coldfield: Jones SL, Milles JJ, Griffiths U, Colloby M, Harold C, Rangan S, Morrison J. Great Western, Swindon: Govindan J, Price P, Ahmed S, Gardner A. Guys & St Thomas Hospital, London: Brackenbridge A, Reid A, Reizer Smith J, Preston J. Hammersmith and Charing Cross: Field BCT, Dornhorst A. Harrogate Hospital: Hammond P, Thirumurugan E, Heartlands Hospital, Birmingham: John R, Patel M, Ulnaf S, Begum S. Hillingdon Hospital, Uxbridge: Edwards M, Doolittle H, Currie A, O'Sullivan S, Lillystone R. Hinchinbrooke Hospital, Huntingdon: Mathews AA. Hull Royal Infirmary: Walton C, Ng B, Kumar BK, Bosomworth A. Ipswich Hospital: Srinath A, Parkinson C, Fowler D, Morris D, Rayman G, Scott A. James Paget Hospital, Great Yarmouth: MacMillan C, Grinnell F. King's College Hospital, London: Lee M, Amiel S, Nathan Y. Kingston Hospital: Oldfield M. Lagan Valley Hospital, Lisburn: Au S, Turtle A. Leicester General Hospital: Targopula G, Braithwaite J, Kong M-F, Jackson S, Gregory R. Leicester Royal Infirmary: Lawrence L, Nisal K. Lincoln County: Sands K. London Medical: King L, Abraham R, Tomeu J. Mayday University Hospital, Croydon: Prentice M. Medway Maritime Hospital, Gillingham: Scobie IN. Monklands Hospital, Airdrie: Sandeep T. Morriston Hospital, Swansea: Stephens JW. Newcastle General: Taylor R. Newham University Hospital, London: Gelding S. Nobles Hospital, Isle of Man: Khan EG, Krishnan A, Clark J, Thondam S. North Manchester General Hospital: Rathur H, Savage M, Wiles P, Prakash P. North Tees & Hartlepol Trust: MacLeod J, Anthony S, Mehaffy J. North Wales NHS Trust, Wrexham: White H. Northampton General Hospital: Hitke ZZ, Kilvert A, Mtemererwa B. Orpington hospital, Kent: Casiglia D. Pinderfields General, Wakefield: Nagi DK. Poole Hospital NHS Foundation Trust: Masding M, Osborne K, Wallace P. PRH, Haywards Heath: Smith A, Mabrook J. Prince Philip Hospital, Llanelli: Williams M, Aggarwal N. Princess Royal, Bromley: Lulsegged A. Queen Alexandra, Portsmouth: Cranston I, Darzy K. Queen Elizabeth II Hospital, Welwyn Garden City: Winocour PH. Queen's Hospital, Burton: Benn J. Raigmore Hospital, Inverness: McLaren L. Rotherham General: Franke B. Royal Berkshire Garden City: Windodur PH. Queen's Hospital, Burton: Benn J. Raighfore Hospital, Inverness: McLaren L. Rothernam General: Hanke B. Royal Berkshire Hospital, Reading: Simpson H, Reddy N, Barber T. Royal Blackburn: Astin J, Faina J, Whalley G, Ramtoola S. Royal Bournemouth: Richards J, Richardson T. Royal Cornwall Hospital, Treliske: Fox T. Royal Devon & Exeter: Bowman P, Hattersley A, Vadiya B. Royal Glamorgan Hospital, Llantrisant: Evans P. Royal Gwent Hospital, Newport: Obuobie K. Royal Infirmary of Edinburgh: Jaap A. Royal Liverpool University Hospital: Vora J, Brake J. Royal Oldham Hospital: Mishra BM. Royal Surrey County Hospital, Guildford: Hordern V. Royal United Hospitals, Bath: Higgs E, Gouni R, Taylor P, Wylie S, Hall B, Hillier N, Neathercote D. RSCH, Brighton: Quin J, Robinson N. Sandwell Hospital, West Bromwich: Ibrahim H, Robertson D, Davies P, Banerjee P, Li YK, Wong KH, Barker N, Dhallu J, Farell D. Scunthorpe General: Moisey R, Malik M, Dromgoole P. Selly Oak Hospital, Birmingham: Creely S, Gough S, Hanif W. Sheffield Teaching Hospitals: Elliott J, Scott A. South East CHCP, Glasgow: Carson L-A. Southampton General Hospital: Sharp P, Brown B. Southern General Hospital, Glasgow: Semple C. St John's Hospital, Livingston: Adamson K, Green F. St Mary's Hospital, Isle of Wight: Kaklamanou M, Al-Mrayat M. St Peter's Hospital, Chertsey: Sennik D, Baxter M, Naqvi S, Suresh D, Miras A. Staffordshire DGH, Stafford: Coates P, Daggett P, Green F. Stirling Royal Infirmary: Kelly C, Mackenzie A, Peden N. Sunderland Royal: Navar R, Carey P, Aspray T. Taunton & Somerset: Close C, Andrews R, Douek I, Watson J. Torbay Hospital, Torquay: Paisey R. University Hospital Coventry Warwickshire: Anderson S. Ulster Hospital, Belfast: Satti N, Harper R, Harding J. Victoria Infirmary, Glasgow: Stewart A. Warwick Hospital: Rao RK, Gopinathan, Horrocks P. West Suffolk Hospital, Bury St. Edmunds: Majeed J, Clark J, Wijenaike N, Gurnell E, Hartley L, Abdullah H, Marath H. Western General Hospital, Content of the stafford stafford stafford in the stafford staffo Edinburgh: Aniello L. Wexham Park, Slough: Dove D. Whipps Cross University Hospital, London: Lakhdar A, Manogaraan B. Wirral Teaching Hospital, Upton Wirral: Leong KS, Lorains J, Joseph P, Leach J, Fenna I. Wishaw General, Lanarkshire: O'Brien I, Davidson E. Worcestershire Acute Hospitals, Worcester: Newrick P, Jenkins D. Wrexham Maelor: Dixon AN, Munigoti S, Stanaway S. Wythenshawe Hospital, Manchester: Younis N. Yeovil District Hospital: Bickerton AST, Crocker M, Down S. York Hospital: Jennings P, Hudson N.

Acknowledgment

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



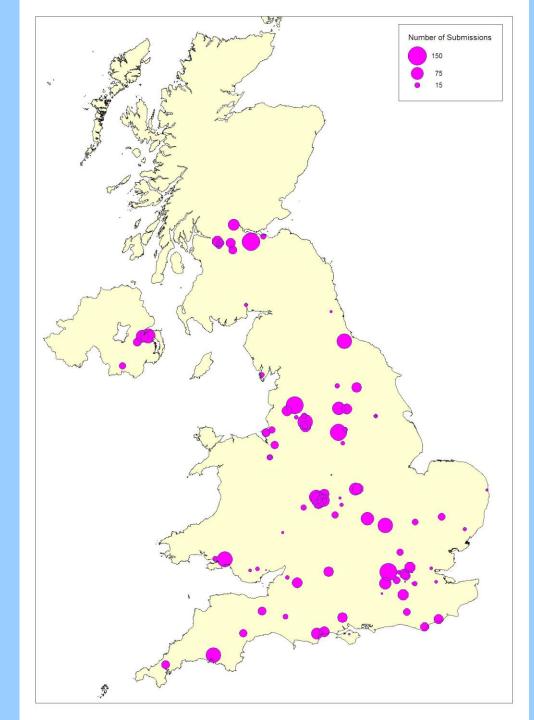




ABCD Nationwide Exenatide Audit









Top contributors > 100 patients

| 1. | Bob Ryder, Hisham Ibrahim, Peter Davies et al, SWBH NHS Trust | 174 |
|-----|---|-----|
| 2. | Karen Adamson, Ferelith Green et al, St John's Hospital, Livingston | 145 |
| 3. | David Dove et al, Wexham Park Hospital, Slough | 137 |
| 4. | Mark Edwards, Helen Doolittle et al, The Hillingdon Hospital, Uxbridge | 136 |
| 5. | Laila King, Ralph Abraham et al, London Medical, London | 134 |
| 6. | Shenaz Ramtoola & Geraint Jones et al, Royal Blackburn Hospital, Blackburn | 133 |
| 7. | Jackie Elliott et al, Sheffield Teaching Hospitals, Sheffield | 119 |
| 8. | Jeffrey W Stephens et al, Morriston Hospital, Swansea | 110 |
| 9. | Richard Paisey et al, Torbay Hospital, Torquay | 104 |
| 10. | Patrick English et al, Derriford Hospital, Plymouth | 104 |
| 11. | Alison Melvin, Julia Pledger & Nick Morrish et al, Bedford Hospital, Bedford | 103 |
| 12. | Julie Mehaffy Jean MacLeod et al, North Tees General Hospital, Stockton-on-Tees | 102 |
| 13. | Phil Coates, Peter Daggett, Gill Green et al, Staffordshire DGH, Stafford | 102 |
| 14. | Mark Savage, Phil Wiles & Parmeshwara Prakash et al, North Manchester General | 101 |



ABCD Nationwide Exenatide Audit

Opening the box on February 18

If only it could have been prospective!



Many spreadsheets many problems

- Lilly Spreadsheets
- Other Non-Standard Spreadsheets
- ABCD Spreadsheets Altered fields added
- ABCD Spreadsheets Altered fields deleted
- Non-Standard Unique ID's used (led to apparent duplication)
- Duplicates record was same patient entered x times on same spreadsheet!
- Missing Dates HbA1c
- Missing Dates Weight
- Missing Dates Lipids
- Data in incorrect columns
- Incorrect Data Heights
- Incorrect Data Weights
- Incorrect Data HbA1c
- Incorrect Data Lipids
- Numbers in Text columns
- Text in Number columns
- Numbers in Date columns
- Dates in Number columns
- Text in Date columns
- Partial Dates
- ? Marks
- X Marks
- N/A
- DNA
- dna
- Transposed columns
- Non Standardised data format
- Not using comments box for comments sticking everywhere else
- Fields renamed



ABCD Nationwide Exenatide Audit

- 7559 patients promised
- 5313 patients had data actually entered
- 3913 data usable



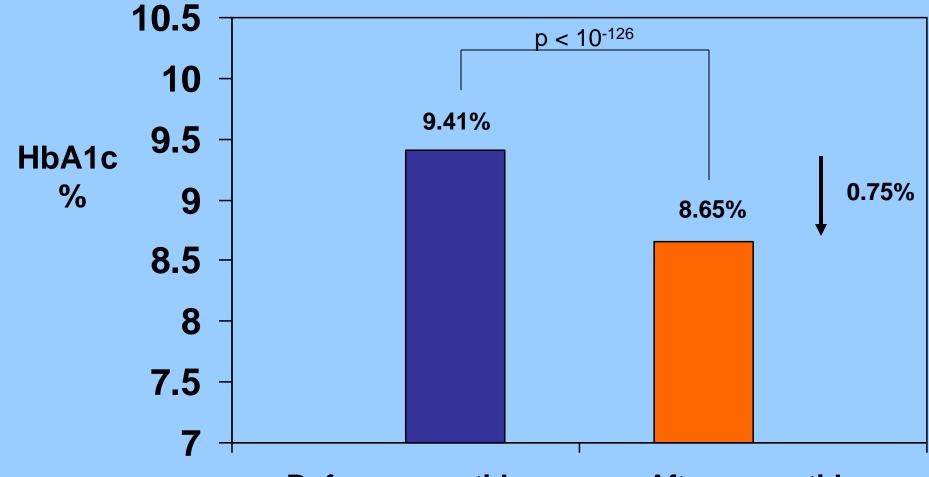
ABCD Nationwide Exenatide Audit

- 7559 patients promised
- 5313 patients had data actually entered
- 3913 data usable



Mean HbA1c before, and last after, exenatide in 3054 patients



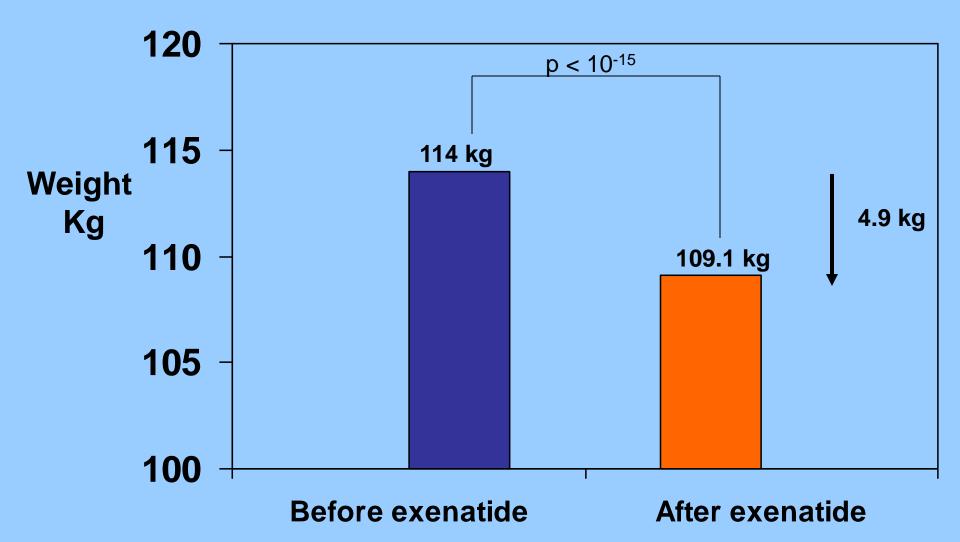


Before exenatide

After exenatide

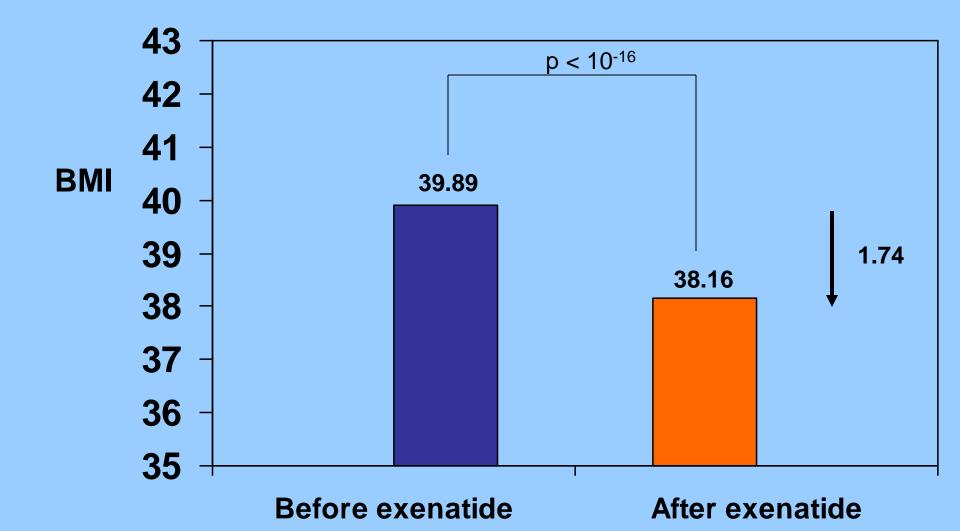
Mean weight before, and last after, exenatide in 2977 patients



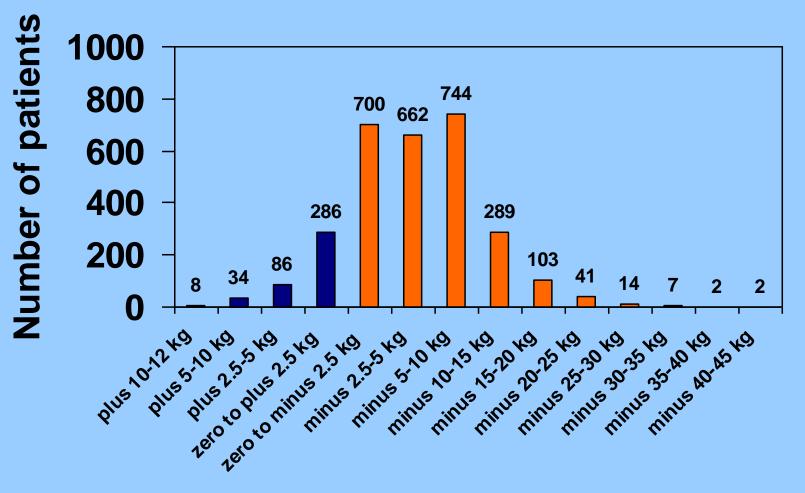


Mean BMI before, and last after, exenatide in 2669 patients





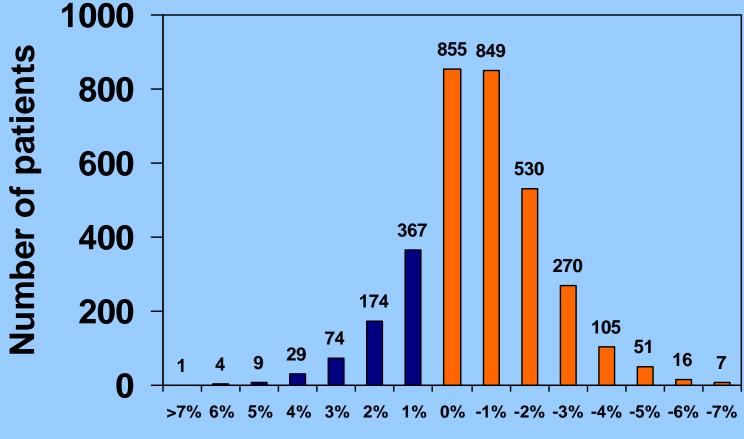
Difference between last weight after exenatide and weight before exenatide



Change in weight after exenatide

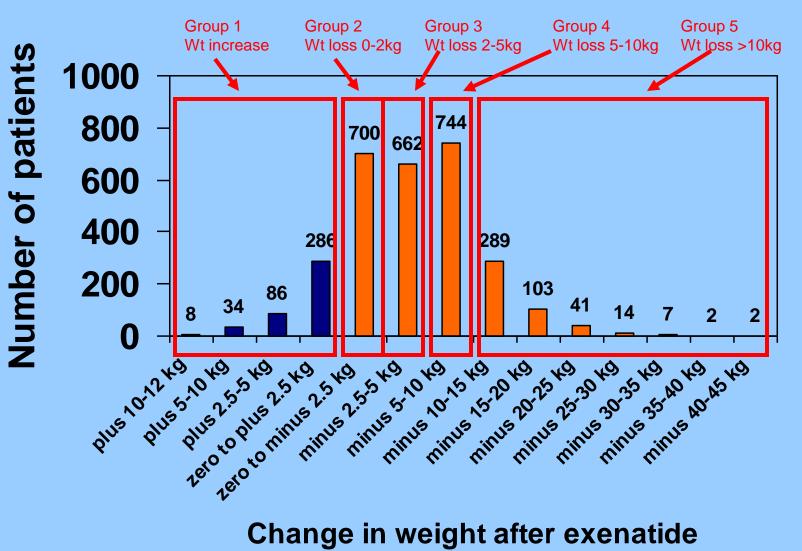
Difference between last HbA1c after exenatide and HbA1c before exenatide





Change in HbA1c after exenatide

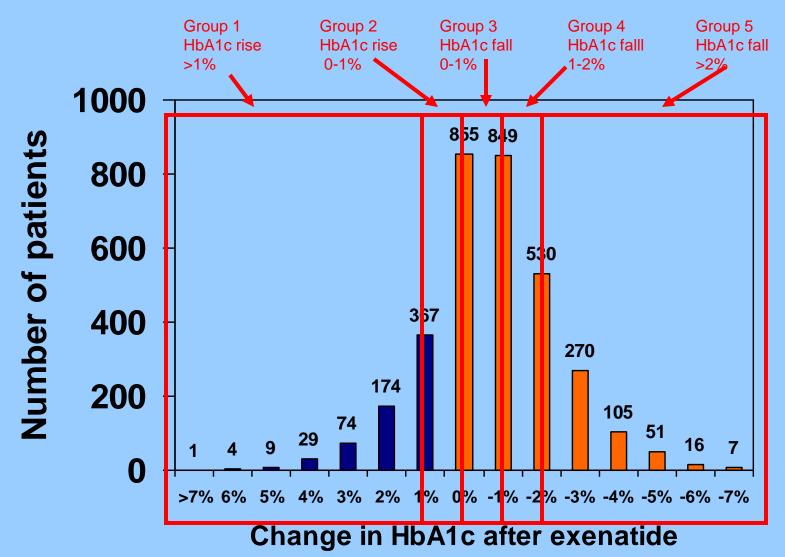
Difference between last weight after exenatide and weight before exenatide



Change in weight after exenatide

Difference between last HbA1c after exenatide and HbA1c before exenatide





Weight and HbA1c groupings



- Any relationship in terms of response between these groupings and:
 - Intial HbA1c
 - Initial weight
 - BMI
 - Duration DM
 - Age
 - Sex
 - On insulin
 - Insulin stopped
 - Other medication changes
 - Eg glitazones stopped, sulphylureas stopped, both these stopped

Weight and HbA1c groupings



- Any relationship in terms of response between these groupings and:
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Weight and HbA1c groupings



- Any relationship in terms of response between these groupings and:
 - Intial HbA1c
 - Initial weight
 - BMI
 - Duration DM
 - Age
 - Sex
 - On insulin
 - Insulin stopped

Weight groupings



- Any relationship in terms of response between these groupings and:
 - Intial HbA1c
 - Initial weight
 - BMI
 - Duration DM
 - Age
 - Sex
 - On insulin
 - Insulin stopped

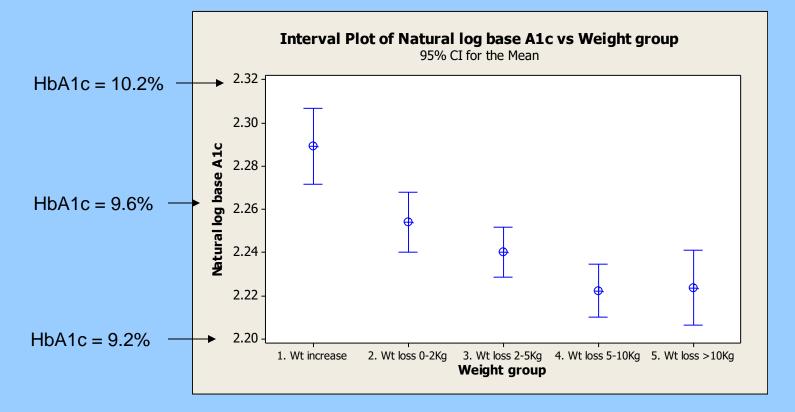
Five weight change groupings

- Group 1 = Weight increase
- Group 2 = Weight loss 0-2Kg
- Group 3 = Weight loss 2-5Kg
- Group 4 = Weight loss 5-10Kg
- Group 5 = Weight loss >10Kg



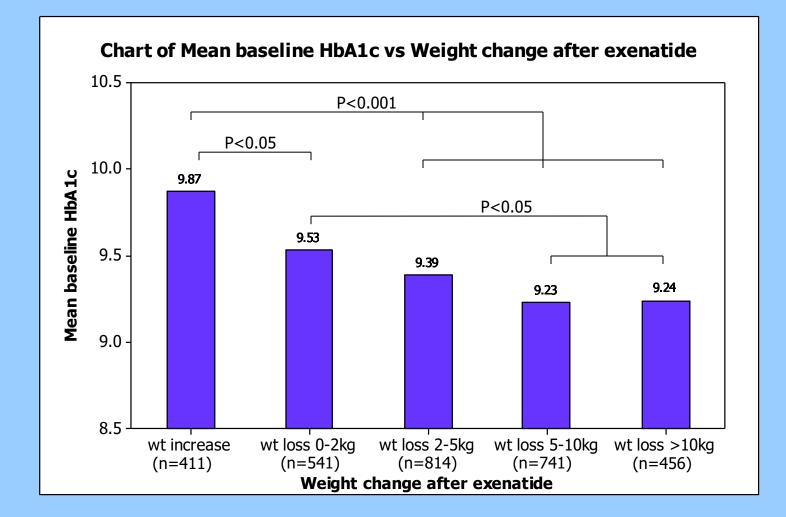
Initial HbA1c in the 5 weight change groupings in 2963 patients





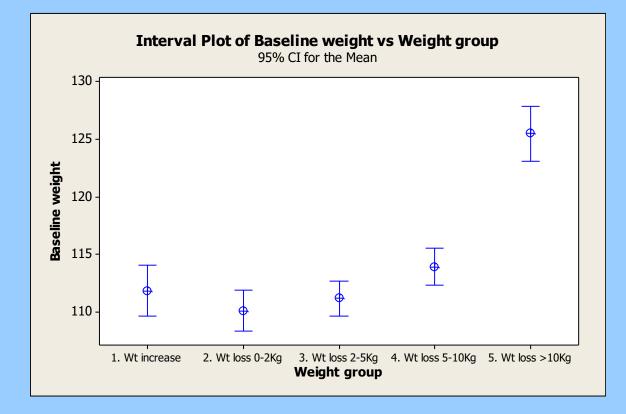
Initial HbA1c in the 5 weight change groupings in 2963 patients





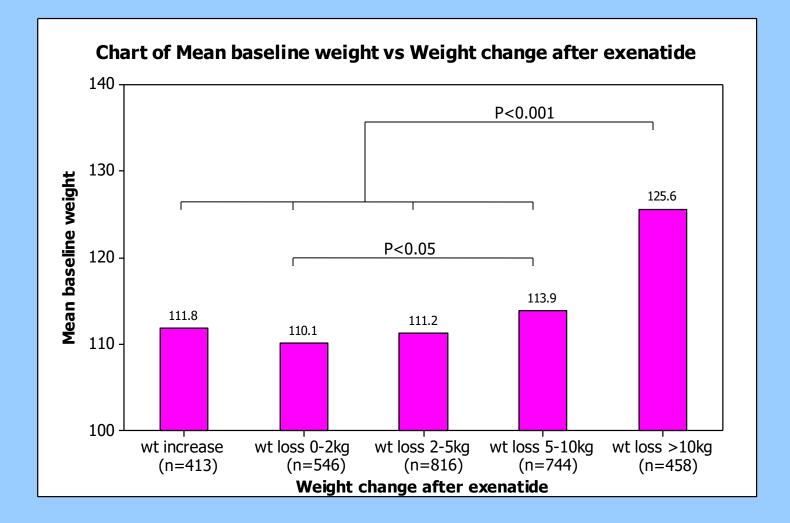
Initial weight in the 5 weight change groupings in 2977 patients





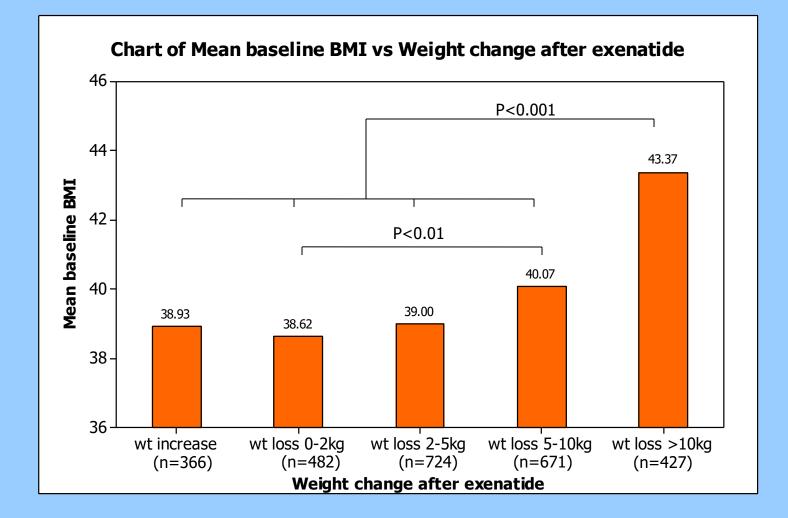
Initial weight in the 5 weight change groupings in 2977 patients





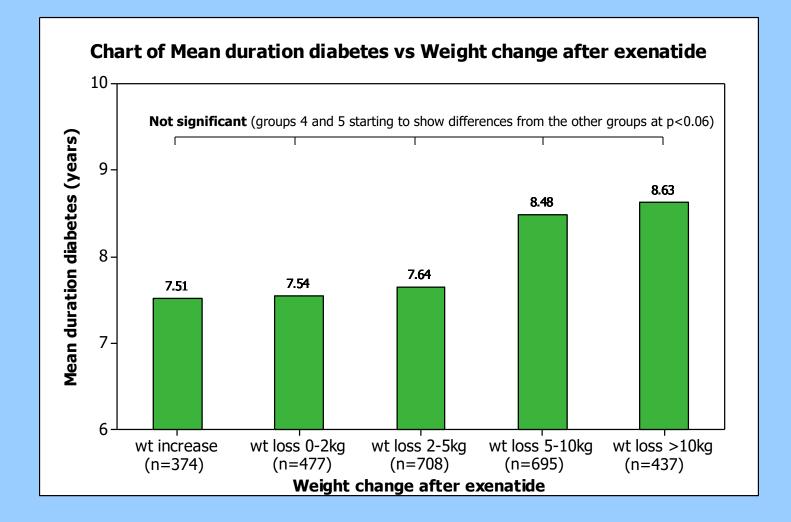
Initial BMI in the 5 weight change groupings in 2670 patients





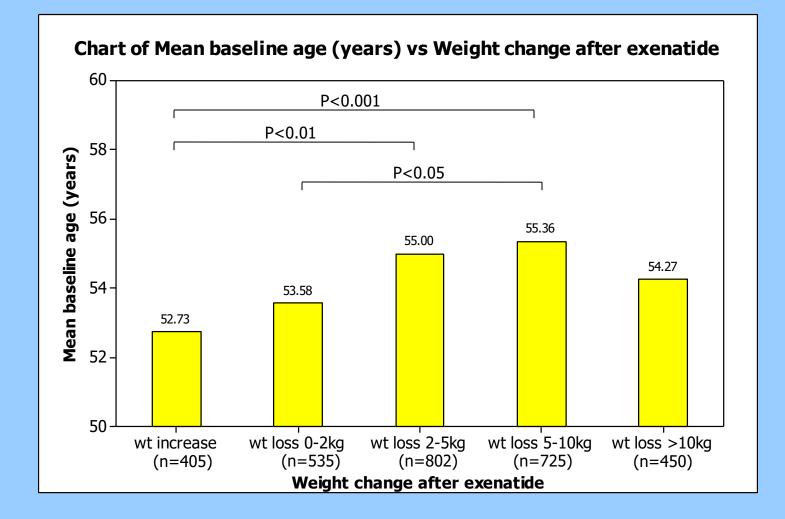
Duration diabetes in the 5 weight change groupings in 2307 patients





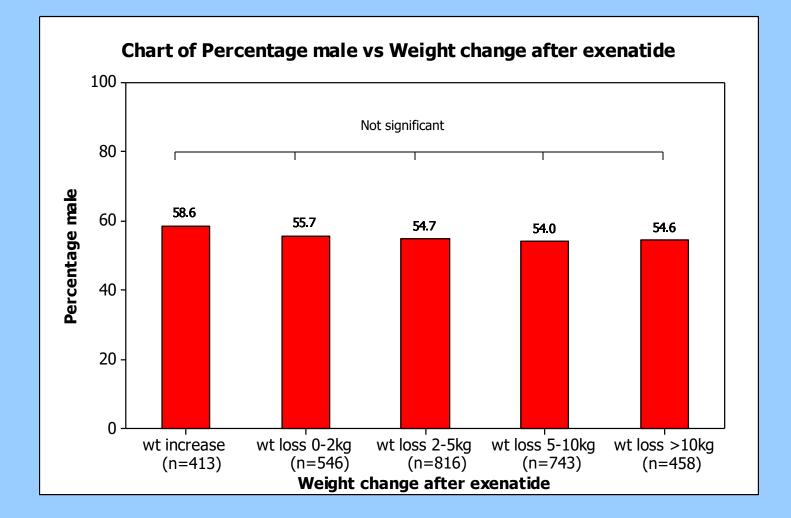
Initial age in the 5 weight change groupings in 2917 patients





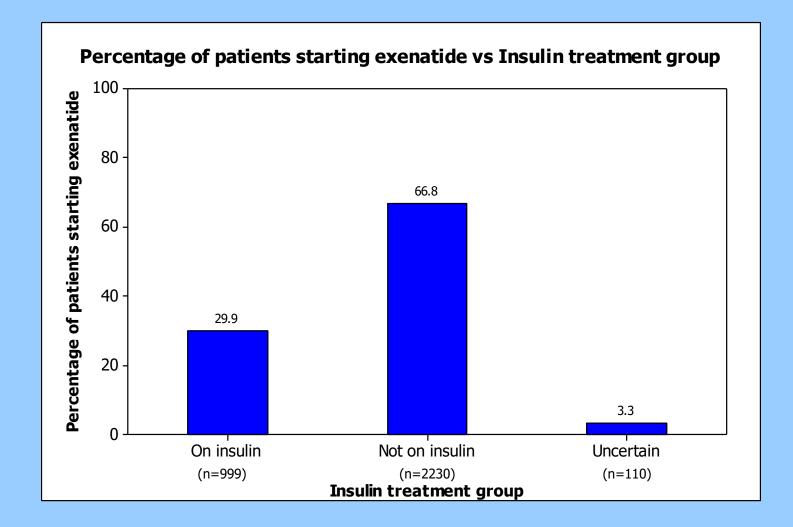
Percentage males in the 5 weight change groupings in 2976 patients





On insulin or not before exenatide in 3339 patients



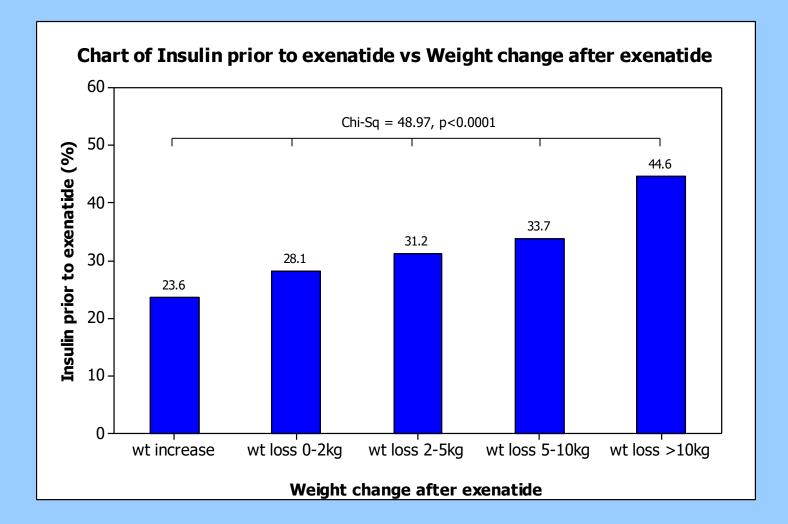






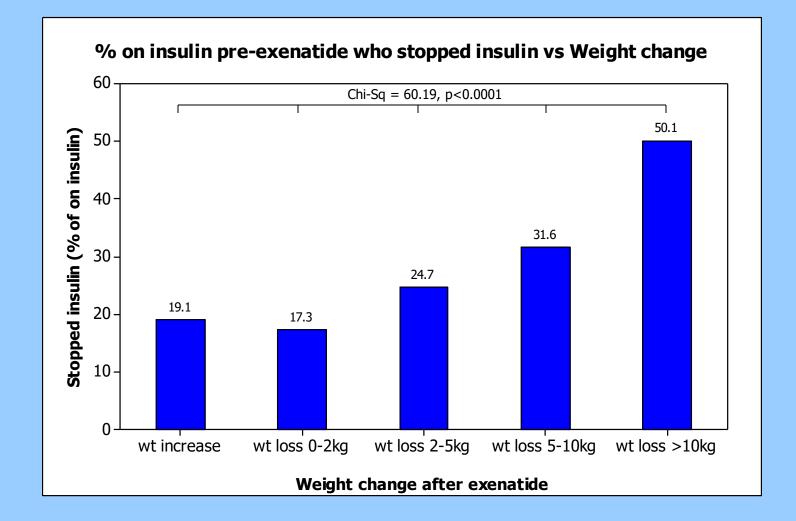
| Code | Category | Number | Percentage |
|------|---|--------|------------|
| 1 | Not on insulin | 2073 | 62.1 |
| 2 | Insulin stopped at start | 194 | 5.8 |
| 3 | Insulin stopped at start, but restarted | 101 | 3.0 |
| 4 | Insulin continued at start | 704 | 21.0 |
| 5 | Not on insulin at start, but added later | 157 | 4.7 |
| 6 | Uncertain | 110 | 3.3 |

Percentage on insulin pre-exenatide in the 5 weight change groupings in 2897 patients









In summary so far



- Those who increase weight, or with lesser degrees of weight loss after exenatide, tend to have higher initial HbA1c, lower initial weight and BM,I and lower age. They are less likely to be on insulin and if on insulin are less likely to have had it stopped.
- Those who lose a large amount of weight after exenatide tend to a lower initial HbA1c, higher initial weight and BMI, slightly longer duration diabetes. They are more likely to have been on insulin and are more likely to have had the insulin stopped.

Anecdote 3: One of the reasons for weight increase on exenatide?

Comment



Female, age 50, on exenatide for 15 months. Previously on pioglitazone and gliclazide

| | Before Exenatide | After Exenatide |
|-------------|------------------|-----------------|
| Data | HbA1c = 12 | HbA1c = 6.8 |
| | Wt = 121 | Wt = 128 Kg |
| | BMI = 42.5 | BMI = 44.8 |
| Weight loss | | -6.7kg |
| HbA1c fall | | 5.2% |

Before exenatide had thirst, polyuria, very tired and thrush. Weight increase may be because weight was low due to poor glycamic control pre exenatide.

•Those who increase weight after exenatide tend to have higher initial HbA1c, lower initial weight and BMI, lower age. They are less likely to be on insulin and if on insulin are less likely to have had it stopped



Female, age 50, on exenatide for 15 months. Previously on pioglitazone and gliclazide

| | Before Exenatide | After Exenatide |
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Comment

Before exenatide had thirst, polyuria, very tired and thrush. Weight increase may be because weight was low due to poor glycaemic control pre exenatide.

Anecdote 1: T2DM & Polycystic ovary syndrome



After Exenatide

Female, age 35, T2DM , on exenatide for 15 months. Insulin was reduced.

Before Exenatide

| Data | HbA1c = 5.7 | HbA1c = 5.8 |
|------|-------------|-------------|
| | Wt = 109.2 | 92 Kg |
| | BMI = 37.8 | BMI = 34.6 |

| Weight loss | 17.2kg |
|-------------|--------|
| HbA1c fall | -0.1% |

Comment

On exenatide periods have returned.

•Those who lose a lot of weight after exenatide tend to a lower initial HbA1c, higher initial weight and BMI, slightly longer duration diabetes. They are more likely to have been on insulin and are more likely to have had the insulin stopped



Female, age 35, T2DM, on exenatide for 15 months. Insulin was reduced.

Before Exenatide

Data

HbA1c = 5.7 Wt = 109.2 BMI = 37.8

HbA1c = 5.8 92 Kg BMI = 34.6

After Exenatide

Weight loss

17.2kg

HbA1c fall

-0.1%

Comment

On exenatide periods have returned.

Anecdote 2: T2DM & Obstructive Sleep Apnoea



and

Female, age 67, on exenatide/metformin for 15 months Prior to exenatide on pioglitazone/metformin

| | Before Exenatide | After Exenatide |
|-------------|--|---|
| Data | HbA1c = 9.6 Wt = 168.4 BMI = 71.9 | HbA1c = 6.5 Wt = 125.2Kg BMI = 53.5 |
| Weight loss | | 43.2 kg |
| HbA1c fall | | 3.1% |
| Comment | Reported an improvement in her breathing a | |

symptoms of obstructive sleep apnoea

•Those who lose a lot of weight after exenatide tend to a lower initial HbA1c, higher initial weight and BMI, slightly longer duration diabetes. They are more likely to have been on insulin and are more likely to have had the insulin stopped



Female, age 67, on exenatide/metformin for 15 months Prior to exenatide on pioglitazone/metformin

| | Before Exenatide | After Exenatide |
|-------------|---|---|
| Data | HbA1c = 9.6 Wt = 168.4 BMI = 71.9 | HbA1c = 6.5 Wt = 125.2Kg BMI = 53.5 |
| Weight loss | | 43.2 kg |
| HbA1c fall | | 3.1% |
| Comment | Reported an improvem | nent in her breathing |

Reported an improvement in her breathing and symptoms of obstructive sleep apnoea

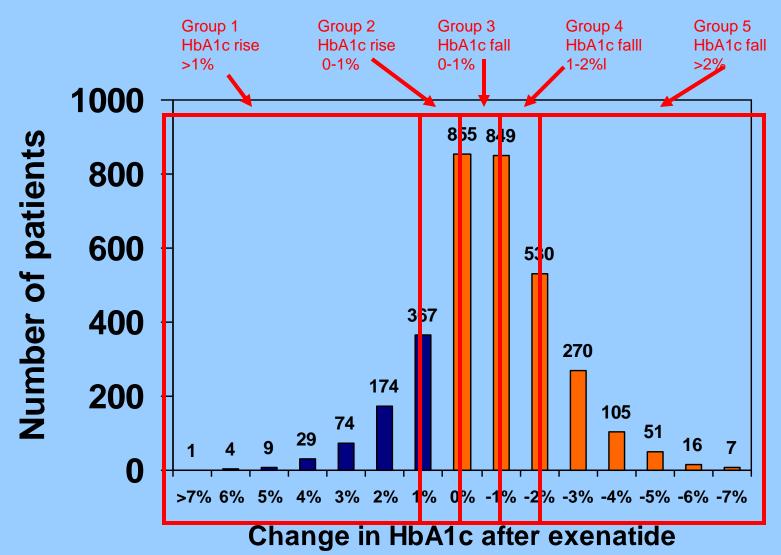
HbA1c groupings



- Any relationship in terms of response between these groupings and:
 - Intial HbA1c
 - Initial weight
 - BMI
 - Duration DM
 - Age
 - Sex
 - On insulin
 - Insulin stopped

Difference between last HbA1c after exenatide and HbA1c before exenatide





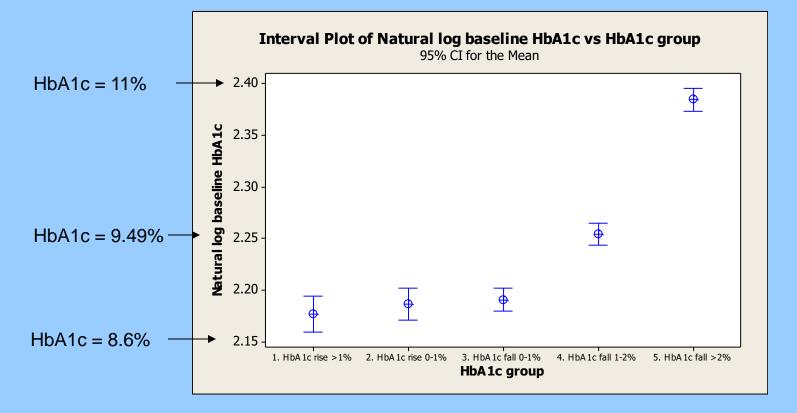
Five HbA1c change groupings

- Group 1 = HbA1c rise >1%
- Group 2 = HbA1c rise 0-1%
- Group 3 = HbA1c fall 0-1%
- Group 4 = HbA1c fall 1-2%
- Group 5 = HbA1c fall >2%



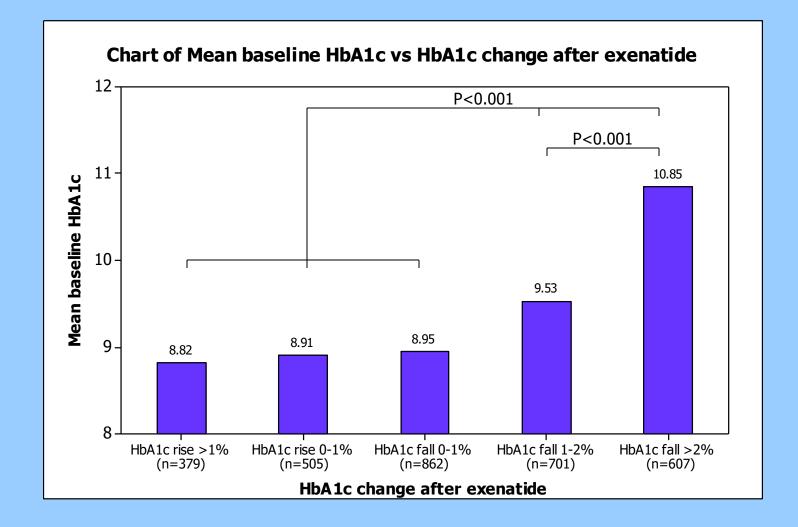
Initial HbA1c in the 5 HbA1c change groupings in 3054 patients





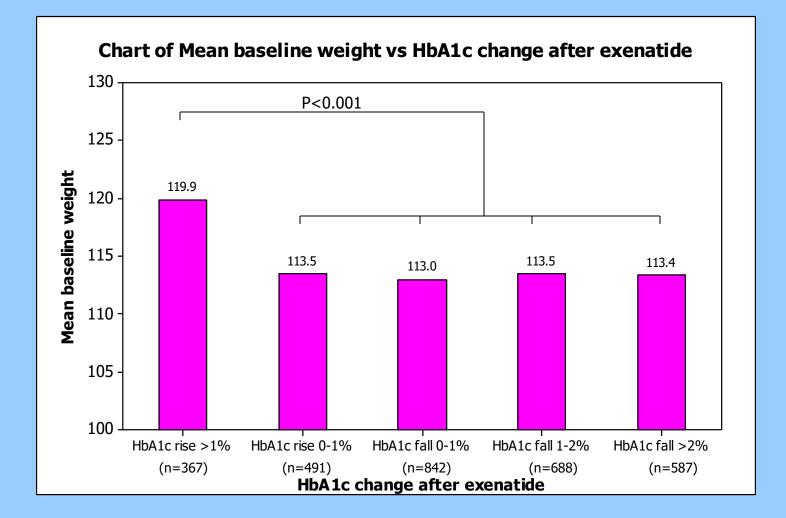
Initial HbA1c in the 5 HbA1c change groupings in 3054 patients





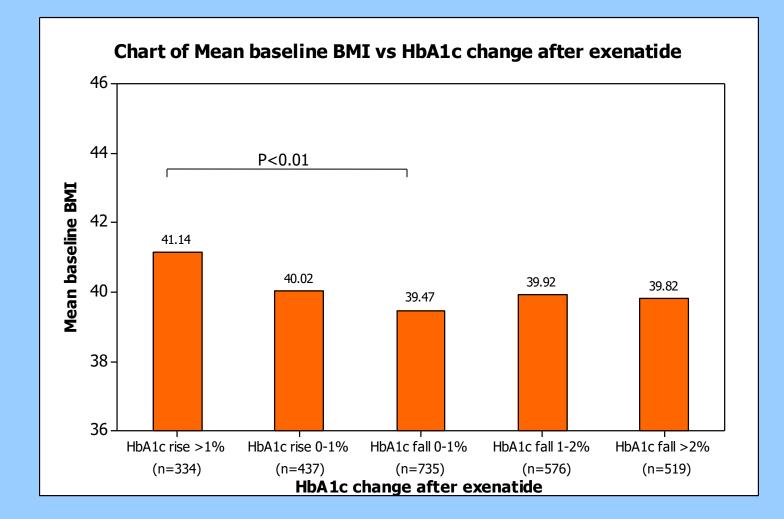
Initial weight in the 5 HbA1c change groupings in 2975 patients





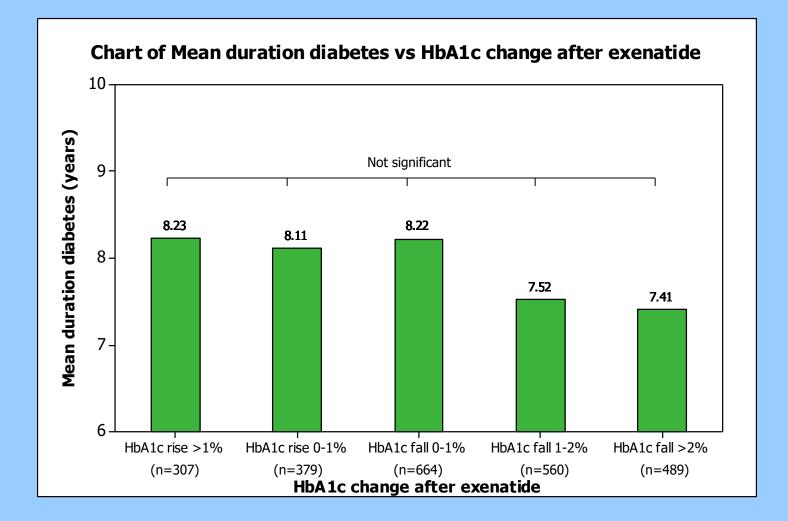
Initial BMI in the 5 HbA1c change groupings in 2601 patients





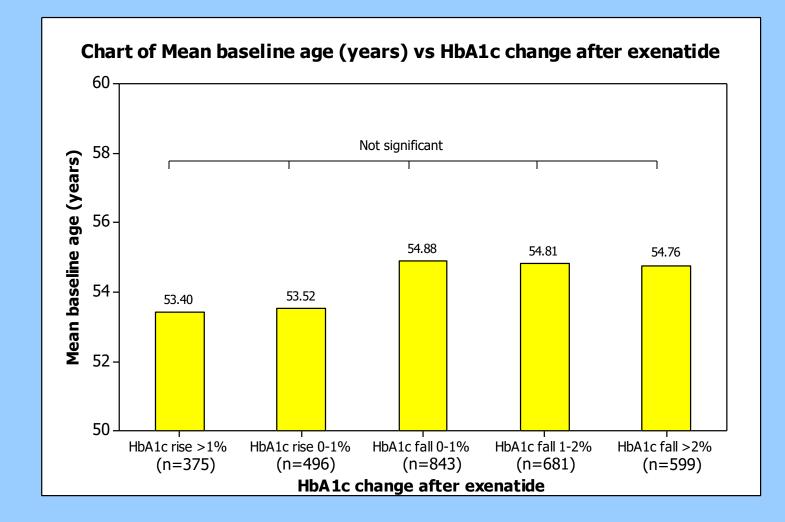
Duration diabetes in the 5 HbA1c change groupings in 2399 patients





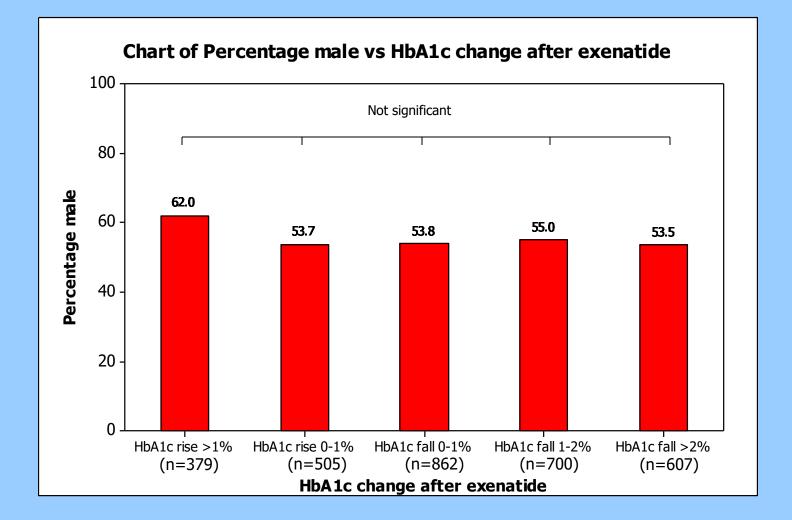
Initial age in the 5 HbA1c change groupings in 2994 patients



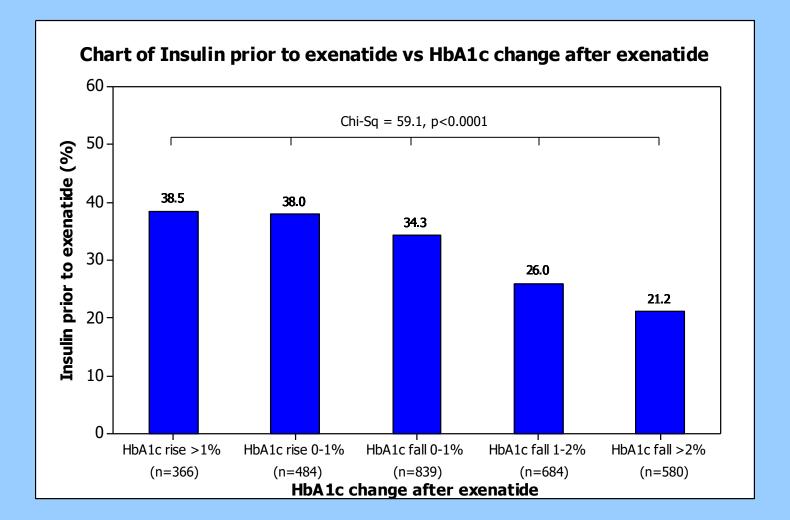


Percentage males in the 5 HbA1c change groupings in 3053 patients



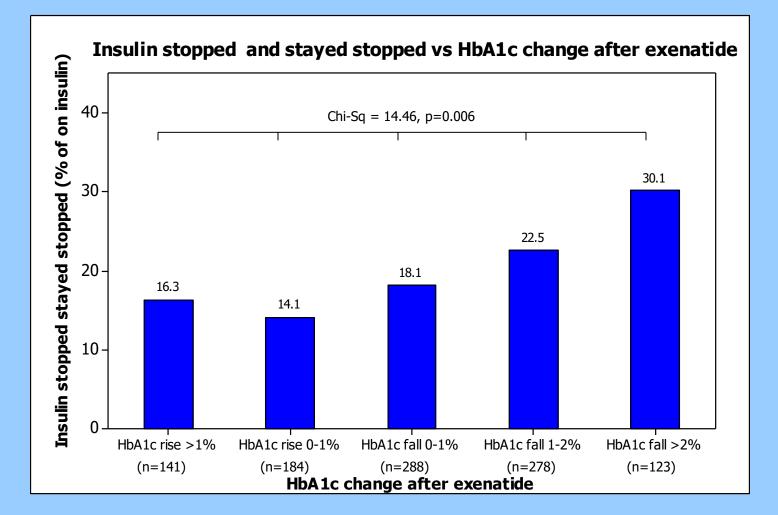


Percentage on insulin pre-exenatide in the 5 HbA1c change groupings in 2953 patients



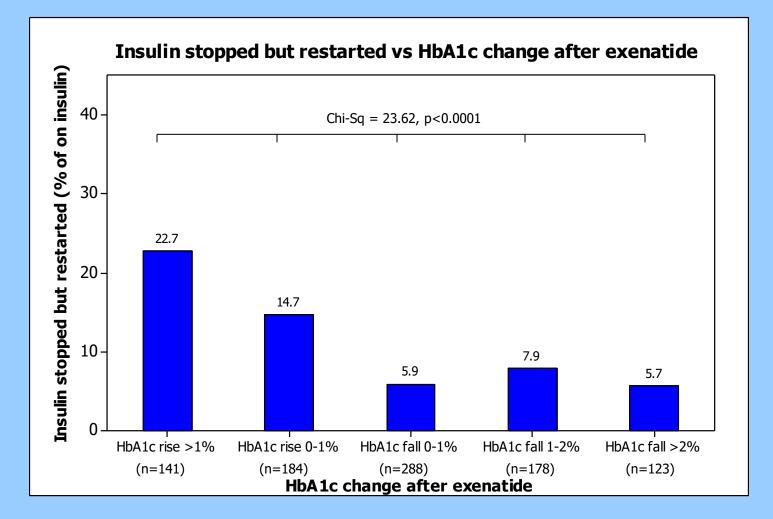
Percentage of the 914 patients on insulin pre-exenatide who stopped insulin and it stayed stopped in the 5 HbA1c change groupings





Percentage of the 914 patients on insulin pre-exenatide who stopped insulin but it was restarted in the 5 HbA1c change groupings





In summary -HbA1c groupings



- Those who with the greatest falls in HbA1c after exenatide had higher initial HbA1c
- Those who experienced the greatest rise in HbA1c after exenatide had a higher initial weight. They were also more likely to be on insulin before being started on exenatide; of those who had their insulin stopped when exenatide was started those with a rise in HbA1c were more likely to have it restarted.

Anecdote 6: Insulin replaced by exenatide – extreme deterioration in HbA1c



Male, age 64, on exenatide for 5 months. Insulin stopped when starting exenatide

Before Exenatide After Exenatide

Medication

Data

Weight loss

HbA1c fall

Metformin 1gm BD Humulin M3 130 iu/day

HbA1c = 7.5% Wt = 113.2 Kg BMI = 37 Metformin 850mg BD Exenatide 10 BD

HbA1c = 15.1 Wt = 99 Kg BMI = 32.3

14.2 kg

-7.6%

Comment

Our highest HbA1c rise after starting exenatide – in a patient who stopped insulin in order to start exenatide

Those who experienced the greatest rise in HbA1c after exenatide had a higher initial weight. They were also more likely to be on insulin before being started on exenatide; of those who had their insulin stopped when exenatide was started those with a rise in HbA1c were more likely to have it restarted.

Male, age 64, on exenatide for 5 months. Insulin stopped when starting exenatide

Before Exenatide After Exenatide

Metformin 1gm BD Humulin M3 130 iu/day

Data

Weight loss

Medication

HbA1c fall

HbA1c = 7.5% Wt = 113.2 Kg BMI = 37 HbA1c = 15.1 Wt = 99 Kg BMI = 32.3

Metformin 850mg BD

Exenatide 10 BD

14.2 kg

-7.6%

Comment

Our highest HbA1c rise after starting exenatide – in a patient who stopped insulin in order to start exenatide



Anecdote 5: Exenatide mistaken for bariatric surgery



Female, age 47, on exenatide for 14 months. Both pioglitazone and gliclazide were stopped

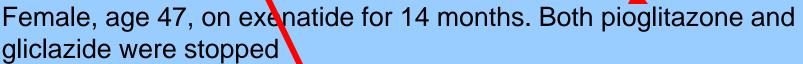
| Data | HbA1c = 8% | HbA1c = 8.7% |
|-------------|-------------|---------------|
| Data | Wt = 152 Kg | Wt = 110.3 Kg |
| | BMI = 52 | BMI = 37.7 |
| Weight loss | | 41.7kg |
| HbA1c fall | | - 0.7% |
| | | |

Comment

Patient was on waiting list for bariatric surgery lost 42 kg in weight on exenatide! At bariatric surgery clinic she was asked by the nurses "when did you have your bariatric surgery!"

Before Exenatide After Exenatide

Those who experienced the greatest rise in HbA1c after exenatide had a higher initial weight. They were also more likely to be on insulin before being started on exenatide: of those who had their insulin stopped when exenatide was started those with a rise in HbA1c were more likely to have it restarted.



| | Before Exenatide | After Exenatide |
|-------------|---|-------------------------------|
| Data | HbA1 = 8% Wt = 152 Kg | HbA1c = 8.7% Wt = 110.3 Kg |
| Weight loss | BMI = 52 | BMI = 37.7 41.7kg |
| HbA1c fall | | - 0.7% |
| Commont | Patient was on waiting list for bariatric surgery lost 42 kg in | |

weight on exenatide! At bariatric surgery clinic she was asked by the nurses "when did you have your bariatric surgery!"

In summary -HbA1c groupings continued



In particular:

- These data suggest that stopping insulin when starting exenatide may lead to worsening of glycaemic control, especially with
 - a higher initial weight

lower HbA1c

 i.e. the heavier, more insulin resistant patient, whose diabetes is currently controlled to some extent by insulin and whose insulin is then stopped

Other side effects



| Total number | 3913 | Percentage of total |
|---------------------------------|------|---------------------|
| Post exenatide hypoglycaemia | 177 | 4.52% |
| Pre exenatide hypoglycaemia | 104 | 2.66% |
| Pancreatitis | 7 | 0.18% |
| Fatigue | 23 | 0.59% |
| Headache | 48 | 1.23% |

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7 pancreatitis cases



- The six centres contacted
- 6/7 were mistakes in data entry!
- 1 actual case though causal relation to exenatide uncertain:

1 pancreatitis case



- Amongst the 4000 patients in the preliminary analysis, there was only one case of acute pancreatitis in a 50 year old male:
 - two admissions with acute abdominal pain prior to exenatide
 - admitted again 4 months after starting exenatide with two weeks of intermittent abdominal pain
 - admitted significant increase in alcohol prior to admission
 - normal amylase on admission
 - acute pancreatitis suggested on CT scan
 - extreme hypertriglyceridaemia (triglycerides 87.8 mmol/L)

Anecdote 4: Eruptive xanthoma

Male, age 46



Before Exenatide After Exenatide

Data

Comment

HbA1c = 12.8 Wt = 156.3 BMI = 51 Cholesterol 17.7 Triglycerides 20.7before



Cholesterol 19.1 Triglycerides 49.5 high

3 – 4 days after starting exenatide developed eruptive xanthoma. Link to exenatide uncertain as had had eruptive xanthoma before in association with starting insulin.

ABCD Nationwide Exenatide Audit

7559 patients promised

5313 patients had data actually entered

• 3913 data usable

 NB information from David Dove of at least one case of fatal pancreatitis among the patients whose data we have but not yet analysed





ABCD Exenatide Audit

 It is not too late to contribute additional cases or update information – we need the last 6 months of HbA1c and weight to draw the graph against time

MTB > desc c1 - c9

Descriptive Statistics: Baseline_HbA, 3MonthHbA1c, 6MonthHbA1c, ...

N N^{*} Mean SE Mean StDev Minimum Variable Q1 Median 0 9.5498 0.0297 1.7112 5.2000 8.4000 9.3000 Baseline HbA1c 3326 3MonthHbA1c 2152 1174 8.8305 0.0391 1.8135 4.9000 7.5000 8.5000 6MonthHbA1c 1200 2122 8.9128 0.0556 1.9274 4.7000 7.5000 8.6000 9MonthHbA1c 504 2820 8.9990 0.0857 1.9245 5.2000 7.5000 8.7000 12MonthHbA1c 279 3041 8.934 0.108 1.806 5.600 7.500 8.700 15MonthHbA1c 98 3221 8.811 0.202 2.004 6.200 7.200 8.300 5.800 7.000 7.700 18MonthHbA1c 0.484 2.421 25 3271 8.736 21MonthHbA1c 4 1101 8.30 1.71 3.42 6.10 6.25 6.85 1.273 24MonthHbA1c 2 516 7.500 0.900 6.600 7.500

| Variable C | Q3 Maximum |
|----------------|-----------------|
| Baseline_HbA1c | 10.6000 17.9000 |
| 3MonthHbA1c | 9.8000 17.5000 |
| 6MonthHbA1c | 10.1000 18.3000 |
| 9MonthHbA1c | 10.3000 16.1000 |
| 12MonthHbA1c | 10.200 13.900 |
| 15MonthHbA1c | 10.200 14.300 |
| 18MonthHbA1c | 10.400 15.000 |
| 21MonthHbA1c | 11.80 13.40 |
| 24MonthHbA1c | * 8.400 |



ABCD Nationwide Exenatide Audit Main conclusion

• We need a research fellow for any future audits!

