

What happens to people with T2DM on o.d. glargine insulin and tablets?

Ian Gallen

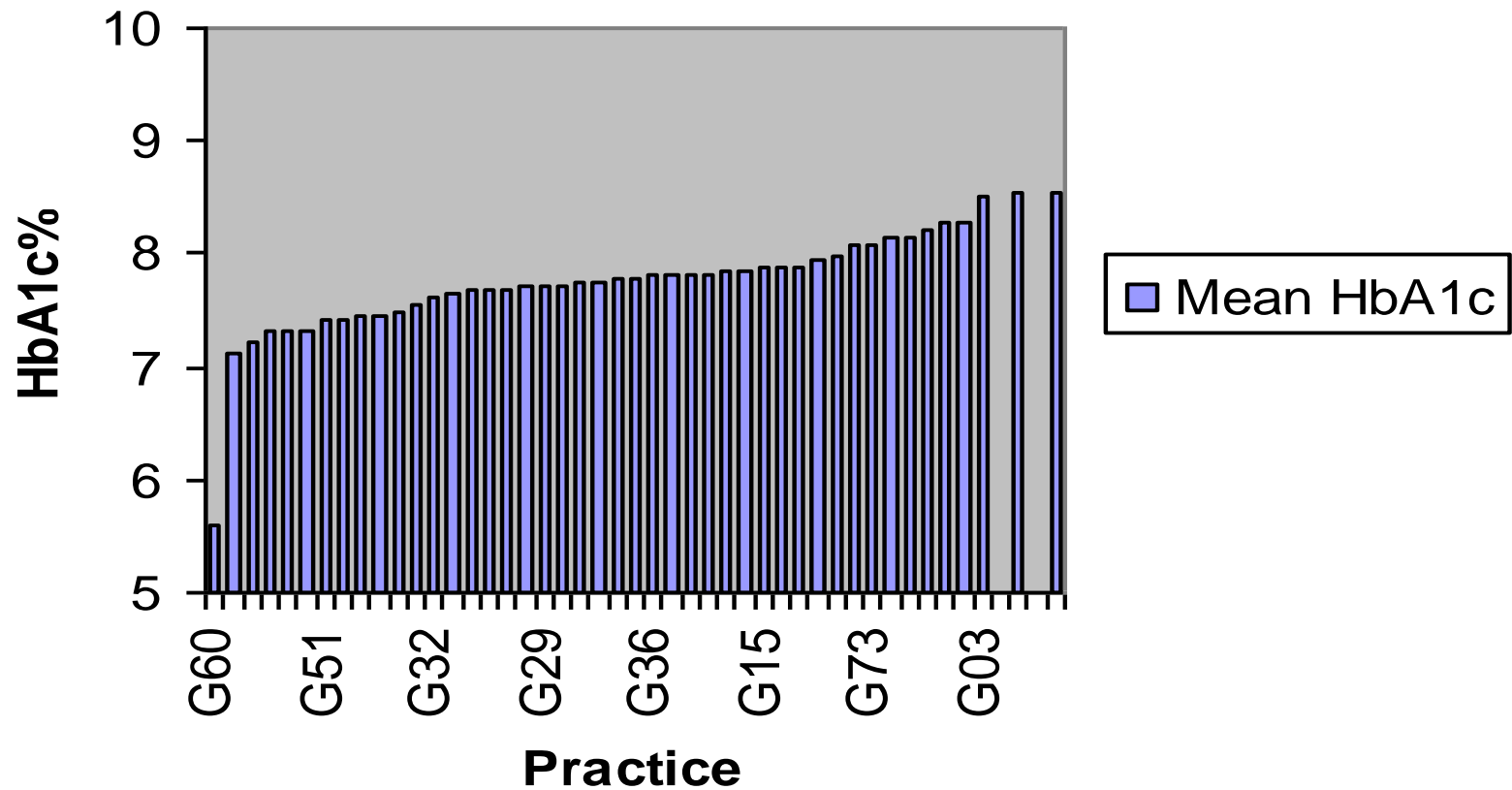






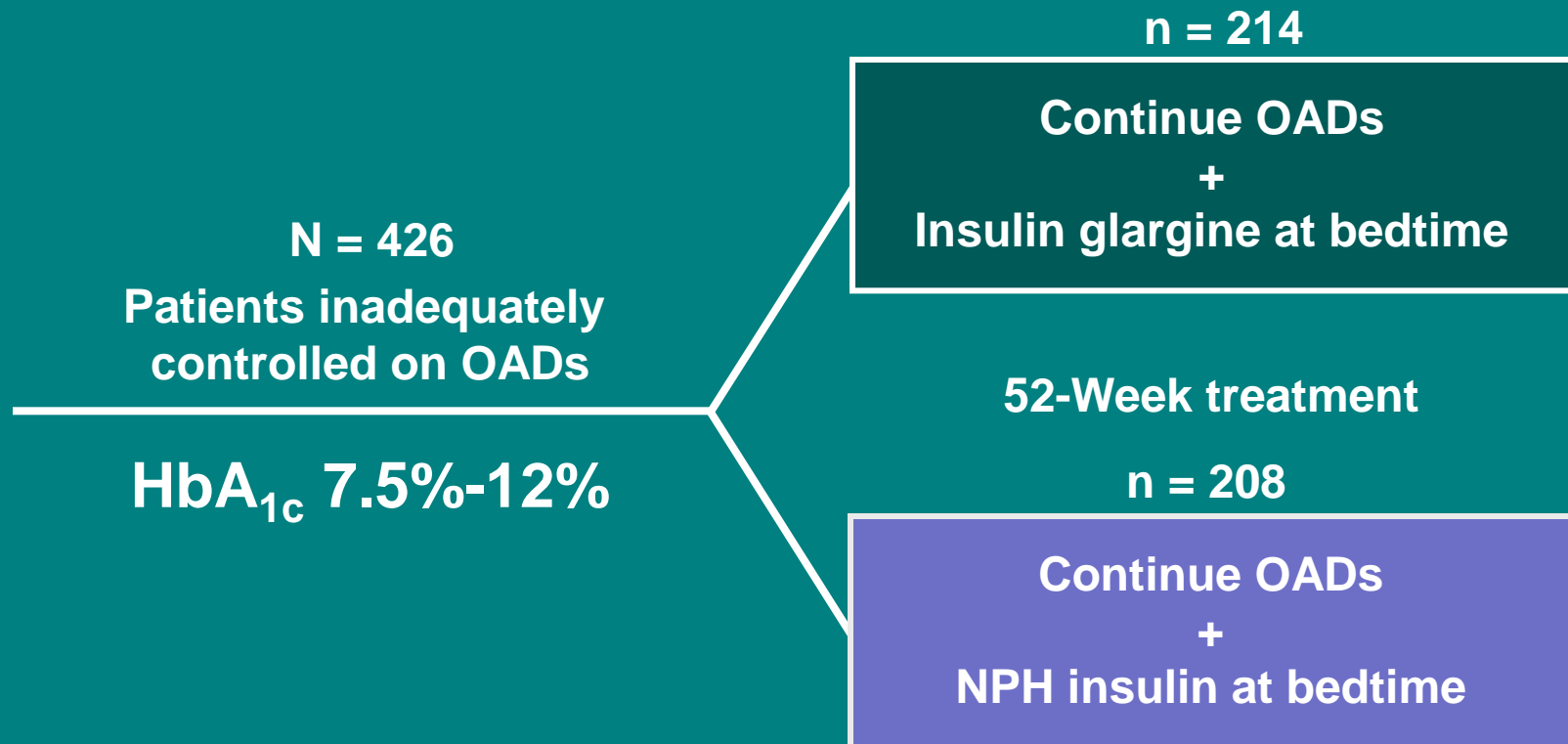
Glycaemic control in Buckinghamshire

Mean HbA1c by GP Practice 2004



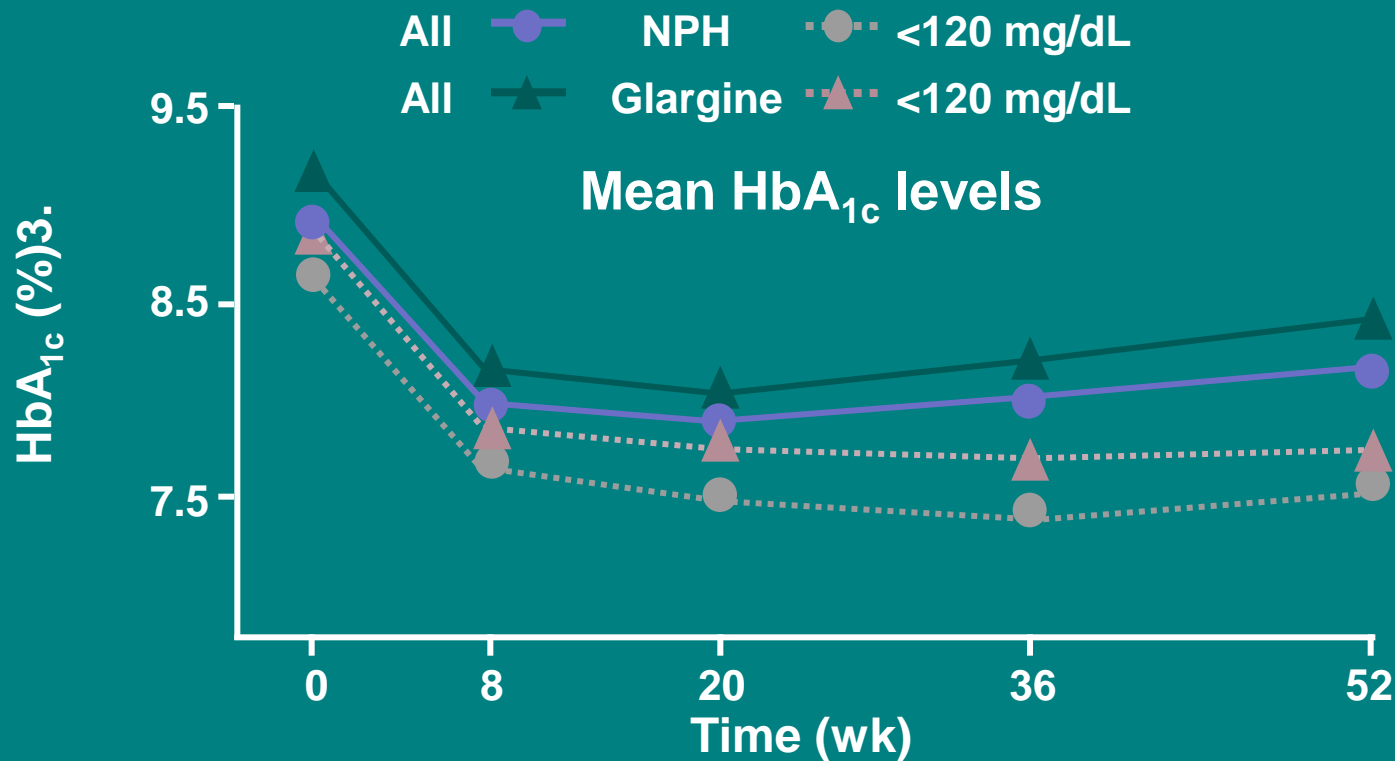
Insulin Glargine vs NPH Insulin Added to Oral Therapy

Target FBG: ≤ 120 mg/dL (≤ 6.7 mmol/L)
Equivalent to FPG ≤ 135 mg/dL (≤ 7.5 mmol/L)

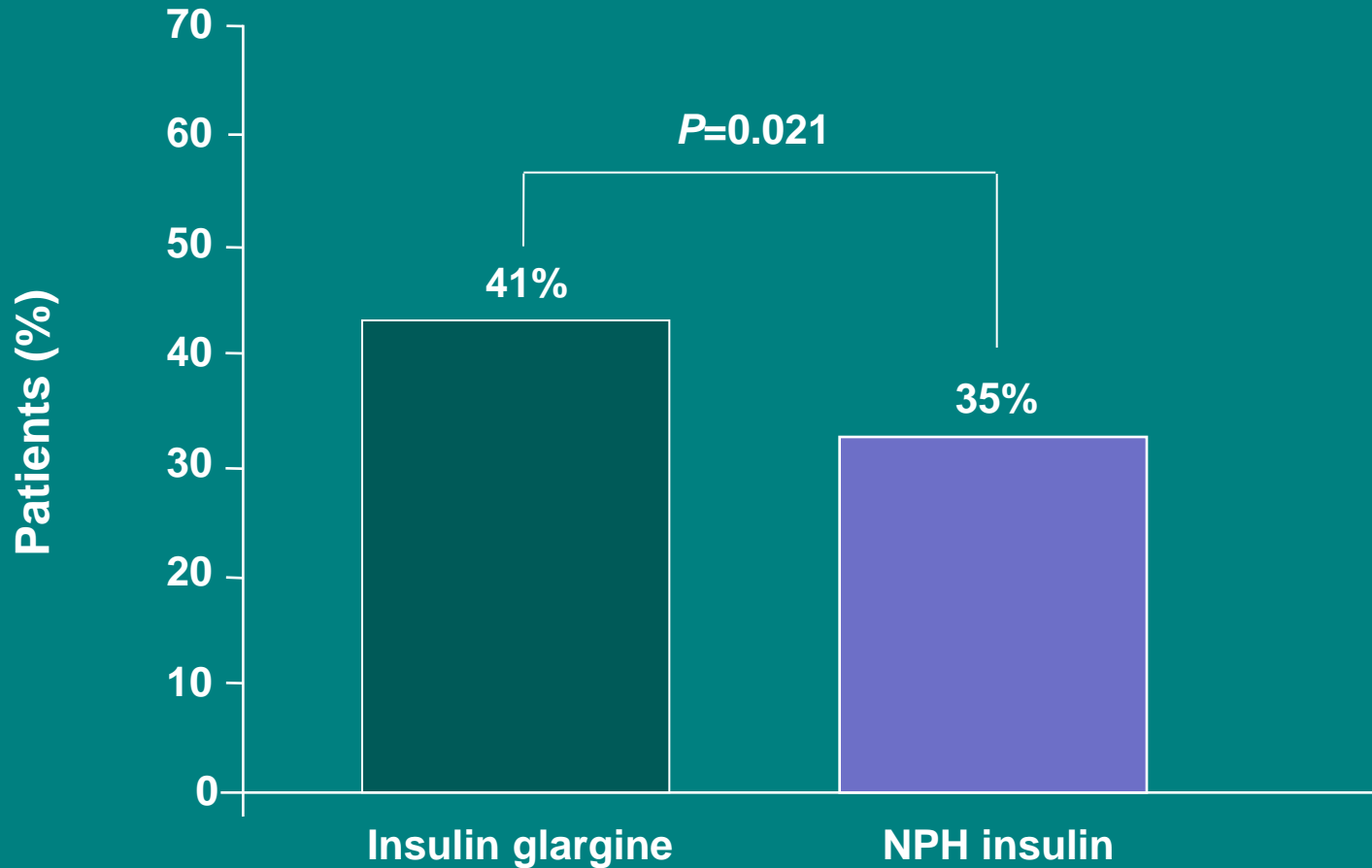


Insulin Glargine vs NPH Insulin Added to Oral Therapy

Target FBG: ≤ 6.7 mmol/L

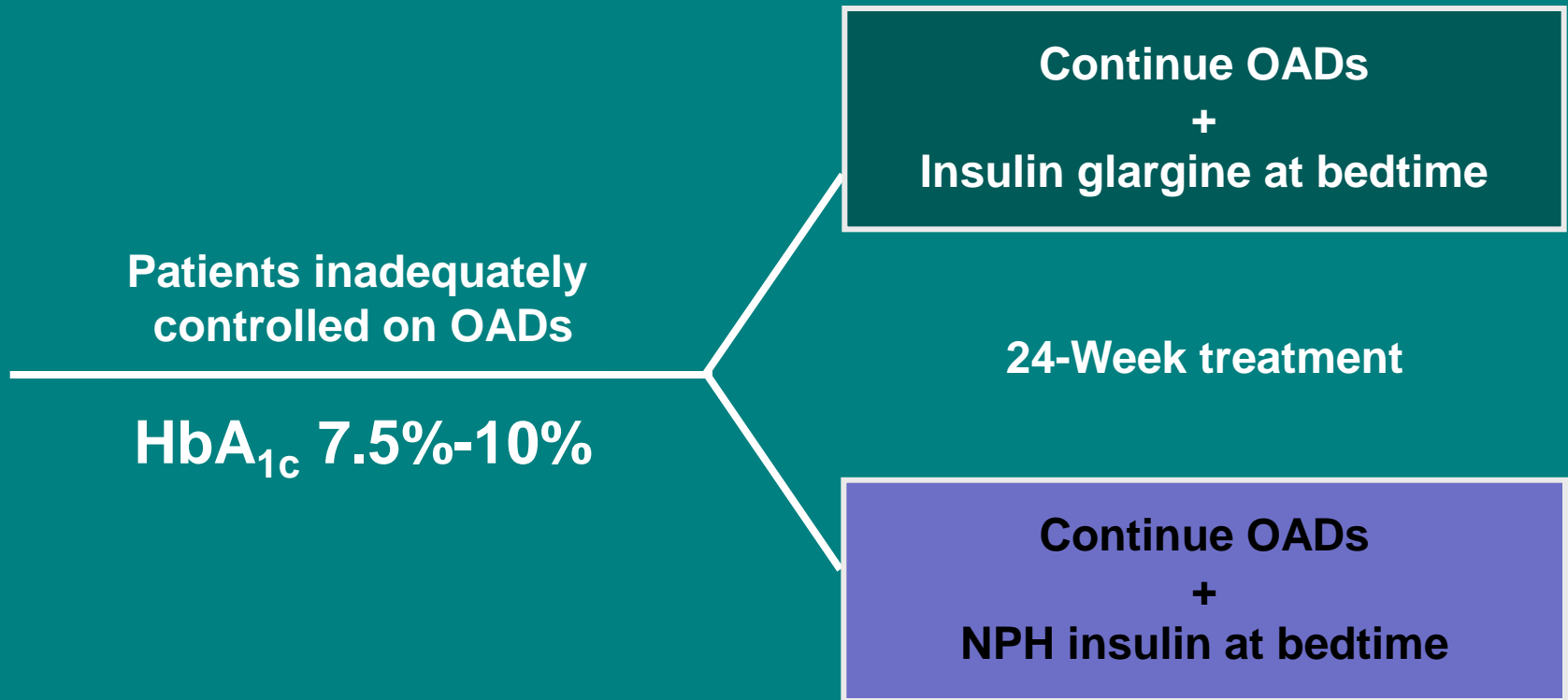


Patients with T2DM with FBG ≤ 6.7 mmol/L at 52 Weeks With Insulin Glargine vs NPH Insulin



Treat-to-Target Trial in T2DM

Target FPG: ≤ 100 mg/dL (≤ 5.5 mmol/L)



Treat-to-Target Trial Methods: Forced-Titration Schedule

Start With 10 IU/d Bedtime Basal Insulin and Adjust Weekly

Self-monitored FPG (mg/dL)*	↑ Insulin Dose (IU/d)†
>180	8
140-180	6
120-140	4
100-120	2

Treat-to-Target ≤ 100 mg/dL (≤ 5.6 mmol/L)

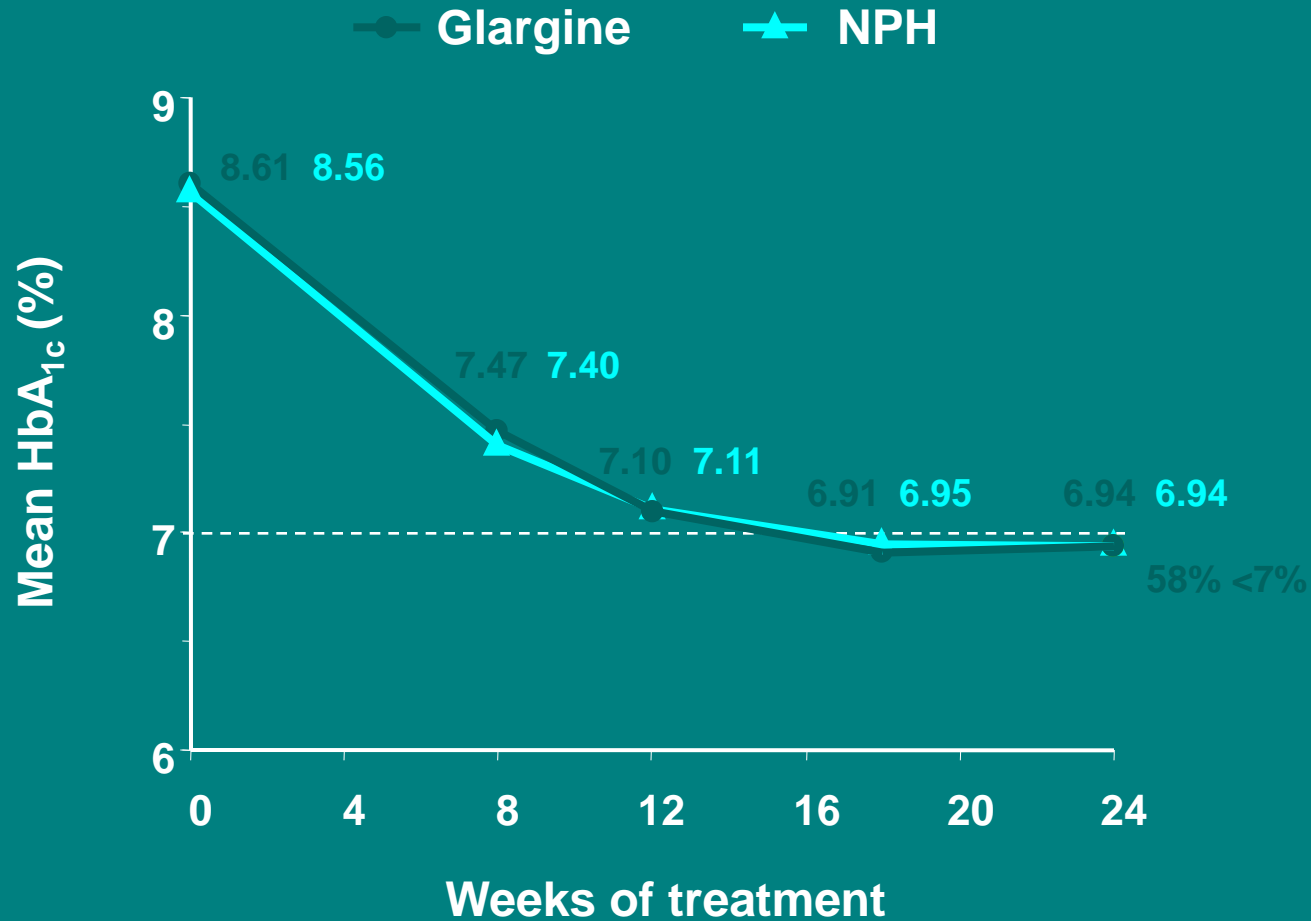
*Measurements were from 2 preceding days; no increase in dosage if PG ≤ 72 mg/dL (≤ 4.0 mmol/L) was documented at any time in preceding week.

†Small decrease (2-4 IU/d) in dosage allowed if self-monitored PG < 56 mg/dL (< 3.1 mmol/L) or severe hypoglycaemia occurs.

FPG=fasting plasma glucose; PG=plasma glucose.

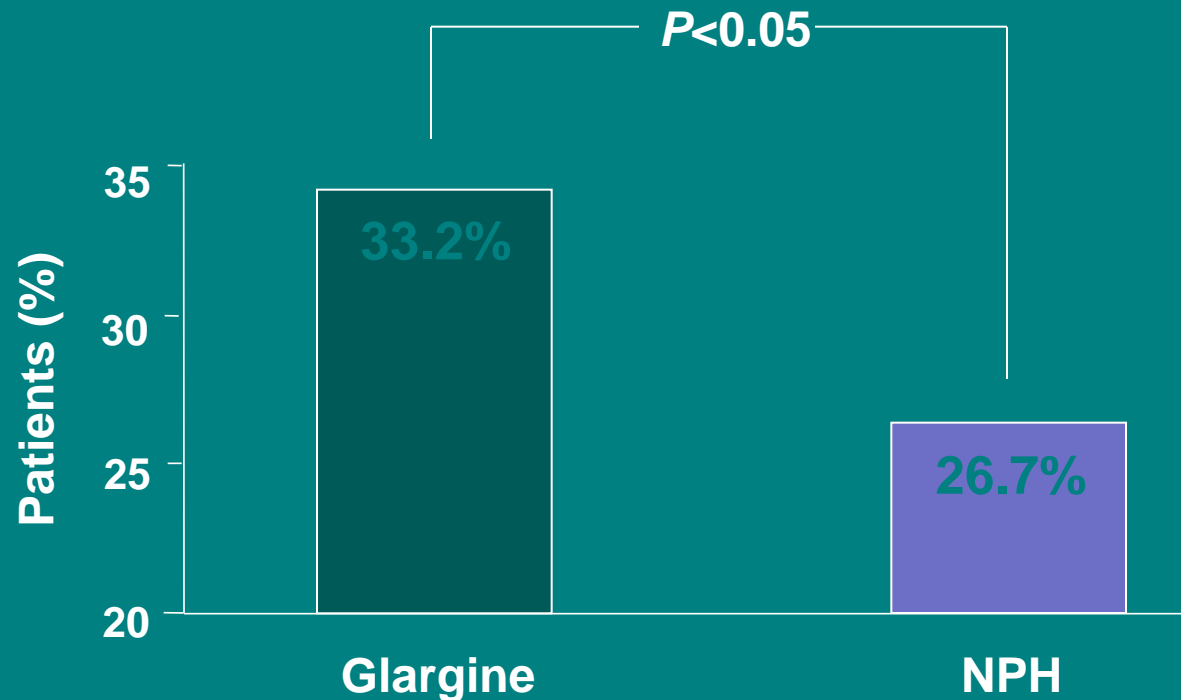
Adapted, with permission, from Riddle M et al. *Diabetes Care*. 2003;26:3080-3086.

Mean HbA_{1c} with Insulin Glargine and NPH Insulin



Treat-to-Target Trial in T2DM: Results

33% of Patients Achieve Target HbA_{1c} ≤7%, Without Documented Nocturnal Hypoglycaemia (PG ≤72 mg/dL [4.0 mmol/L]), With Insulin Glargine

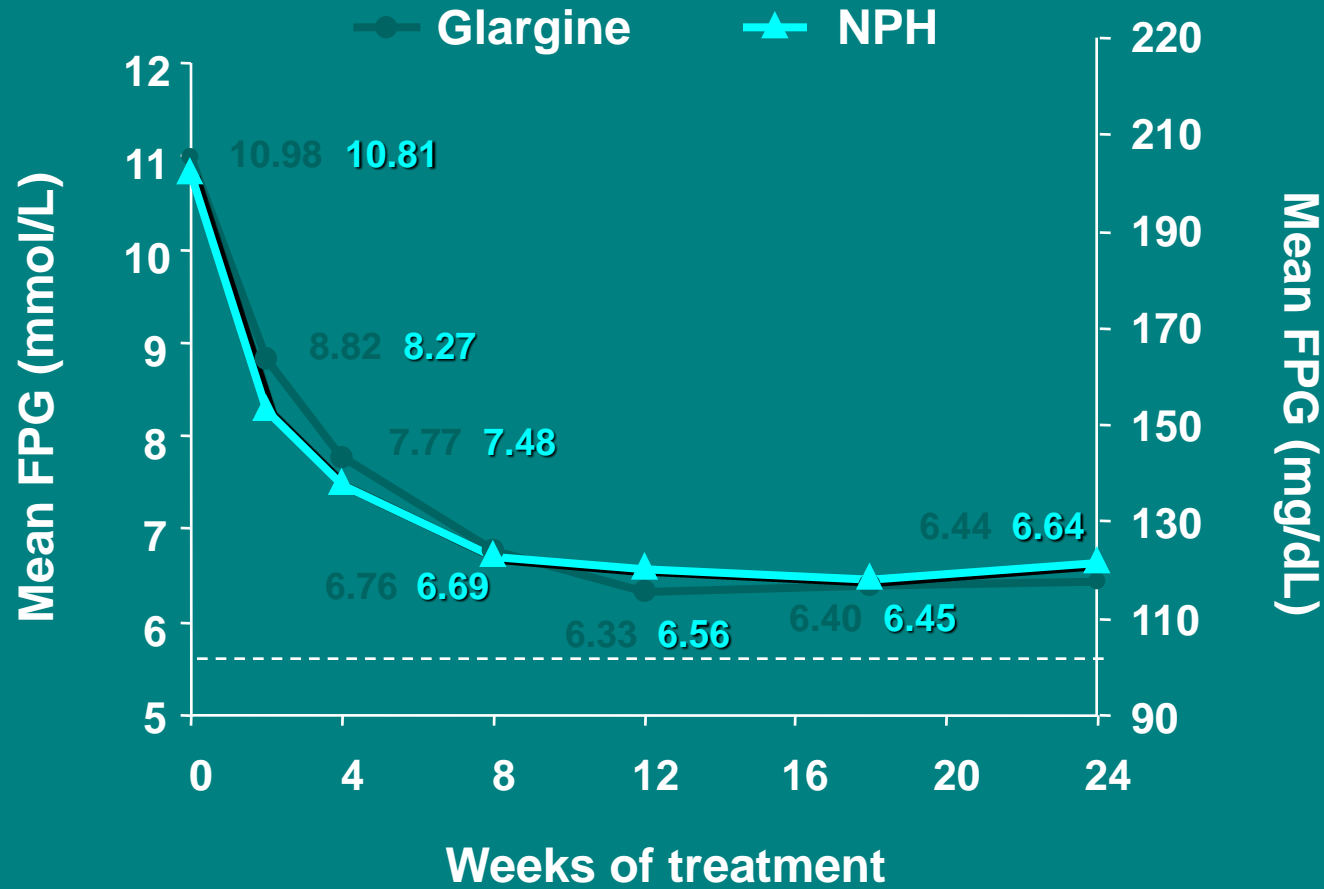


Intent-to-treat analysis.

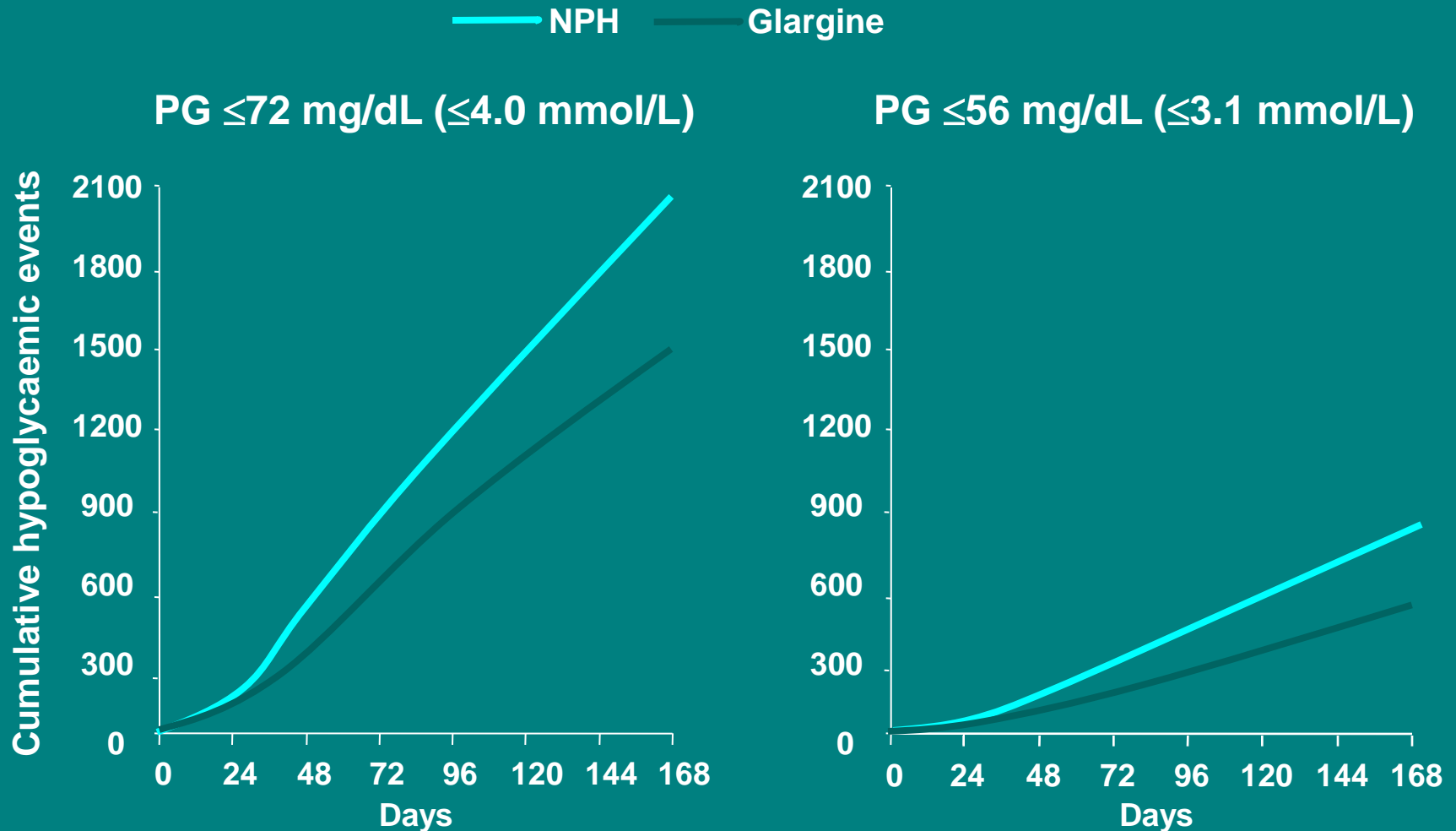
PG=plasma glucose; NPH=neutral protamine Hagedorn.

Adapted from Riddle M et al. *Diabetes Care*. 2003;26:3080-3086.

Sustained FPG Reductions Are Achieved During Study With Insulin Glargine and NPH Insulin



Incidence of Hypoglycaemia With Insulin Glargine vs NPH Insulin



Hypoglycaemic Events With Insulin Glargine vs NPH Insulin

No. of Hypoglycaemic Events per PY	Glargine	NPH	<i>P</i> Value	Relative Risk Reduction, %
All symptomatic	13.9	17.7	<0.02	21
Confirmed ≤ 4 mmol/L (≤ 72 mg/dL)	9.2	12.9	<0.005	29
Confirmed ≤ 3.1 mmol/L (≤ 56 mg/dL)	3.0	5.1	<0.003	41

Nocturnal Hypoglycaemic Events With Insulin Glargine vs NPH Insulin

No. of Nocturnal Hypoglycaemic Events per PY	Glargine	NPH	<i>P</i> Value	Relative Risk Reduction, %
All nocturnal symptomatic	4.0	6.9	<0.001	42
Confirmed nocturnal ≤ 4 mmol/L (72 mg/dL)	3.1	5.5	<0.001	44
Confirmed nocturnal ≤ 3.1 mmol/L (56 mg/dL)	1.3	2.5	<0.002	48

Glargine-T2DM in Wycombe

- October 2003-until October 2004
- 105 people with **T2 DM** (77 male, 83 Caucasian, 20 South-Asian, 2 other ethnicity)
- 75 (77%) were treated with **GLAR+MET**
- Sulphonylurea **SU** agents 88 (84%), thiazolidinediones **TZD** 22(21%), and Repaglinide/Nateglinide **MEG** 6 (7%) were stopped
- **GLAR** monotherapy in 20 (23%).

Methods

- Group starts of 6-10 in Wycombe Diabetes Centre
- 4 times 2 hour group session with DSN, and 30 minutes with dietician
- Translator group for SA patients (Urdu/Punjabi)
- Minimum of 4 telephone contacts for dose titration
- Requested 4 point SBGM 3 times weekly
- TTT titration protocol
- No additional measurements or questionnaires

Baseline data

		<i>n</i>	%
Sex	Male	71	67%
	Female	34	33%
Race	Caucasian	83	80%
	South Asian	20	17%
	Other	2	3%

Baseline data

	Mean	SD	Min	Max
Age (years)	59.1	12.0	35.0	83.0
Weight (kg)	89.0	22.0	53.3	153.4
Height (m)	1.7	0.1	1.5	1.9
Body mass index (kg/m ²)	30.5	7.4	18.0	55.8
HbA _{1c} (%)	9.5	1.4	7.2	15.2
Fasting blood glucose (mmol/L)	10.4	3.1	5.0	22.0
Time since diagnosis (years)	7.2	4.6	0.0	25.0
Duration of oral therapy (years)	5.3	3.0	1.0	13.0

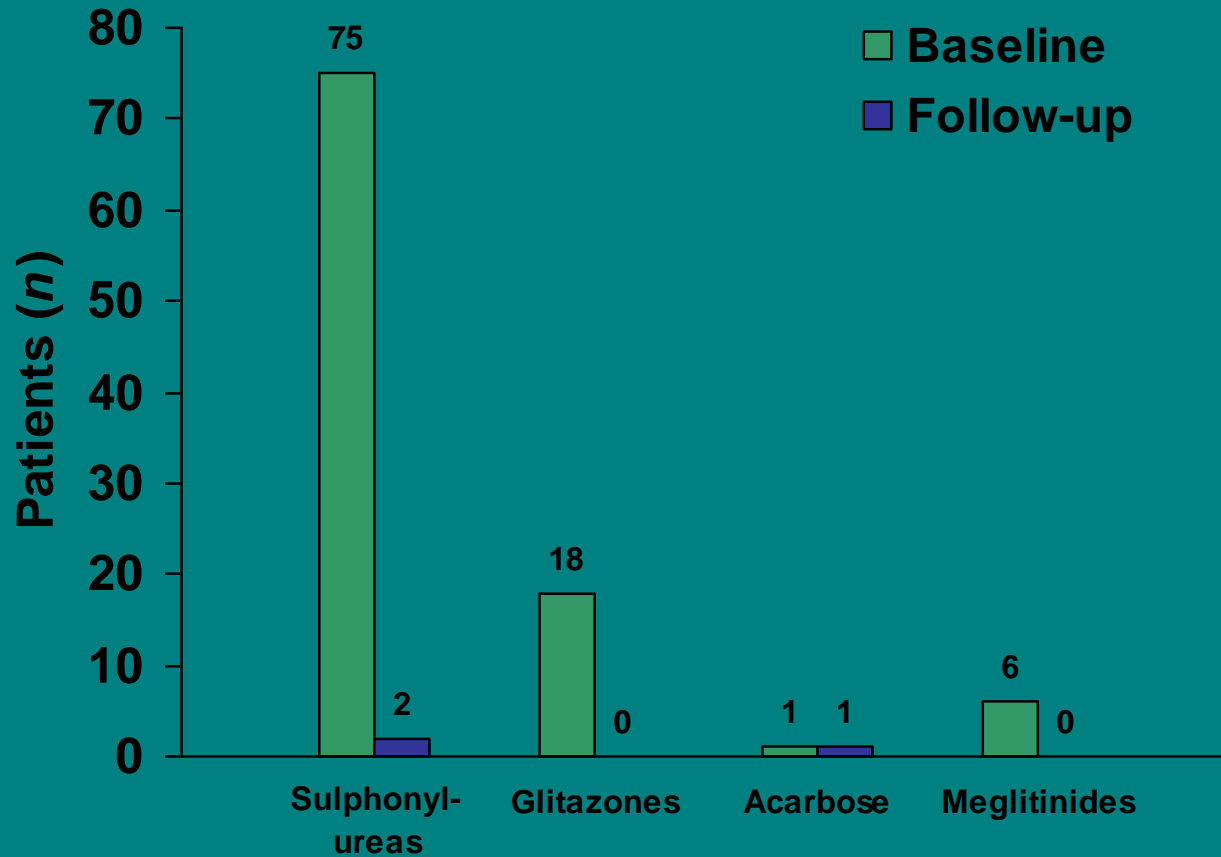
Baseline data

		%	
Time since diagnosis	0–5 years	46%	
	5–10 years	33%	
	10–15 years	16%	
	>15 years	6%	
Duration of oral therapy	0–5 years	63%	
	5–10 years	31%	
	>10–15 years	6%	
Mild hypos in past month	0	97%	
	1	1%	
	2	2%	
Severe hypos in past month	0	100%	

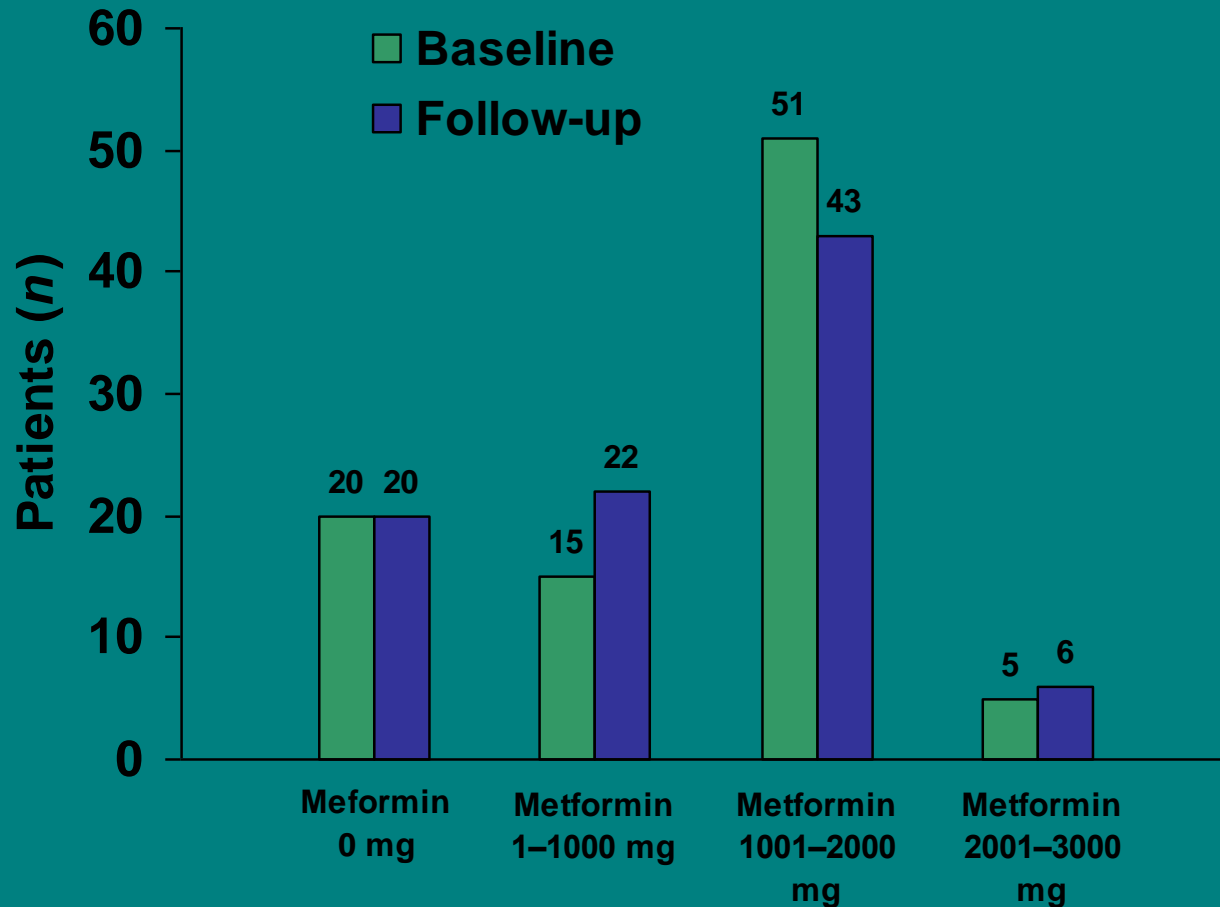
Baseline data

		%
Complications	Retinopathy	16%
	Nephropathy	10%
	Cardiovascular	15%
	Other vascular	4%
	Neuropathy	21%
	Lipodystrophy	
	Foot disease	2%
	Impotence (men only)	7%

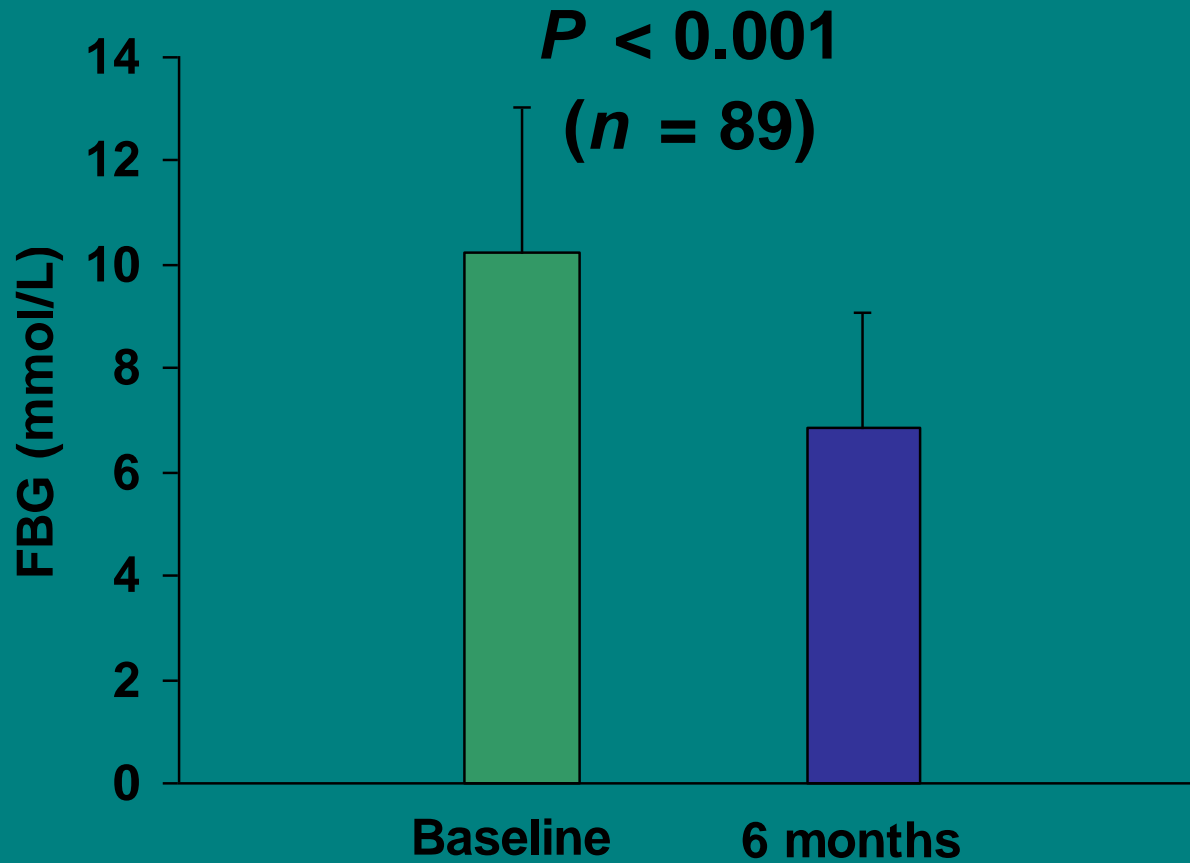
Other anti-diabetic therapies



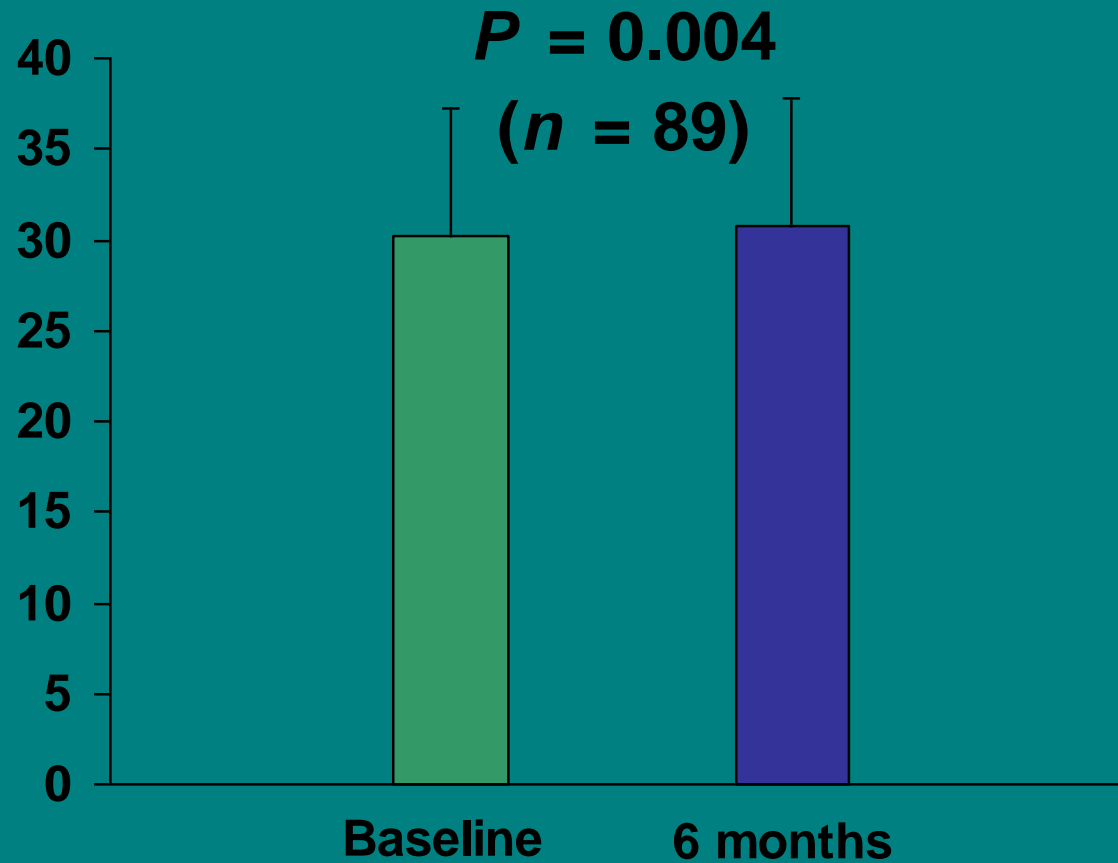
Other anti-diabetic therapies



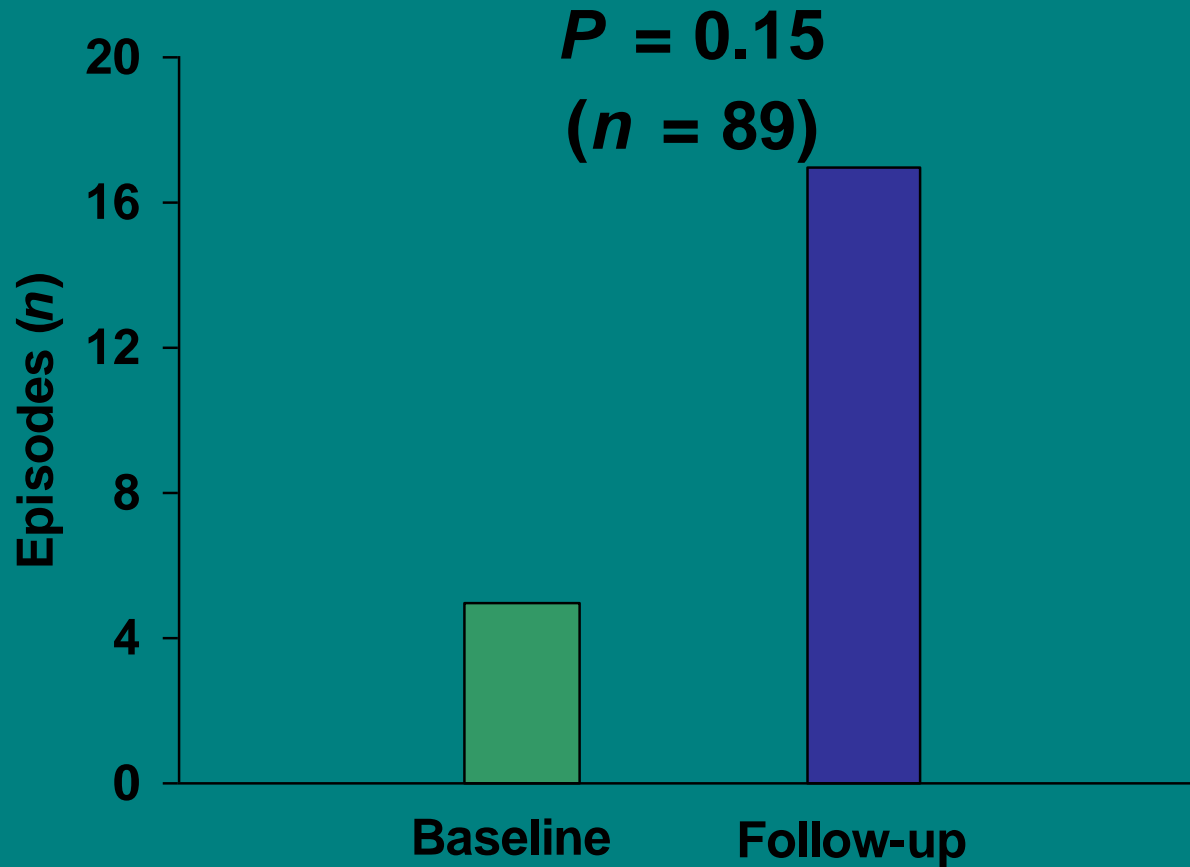
Fasting blood glucose



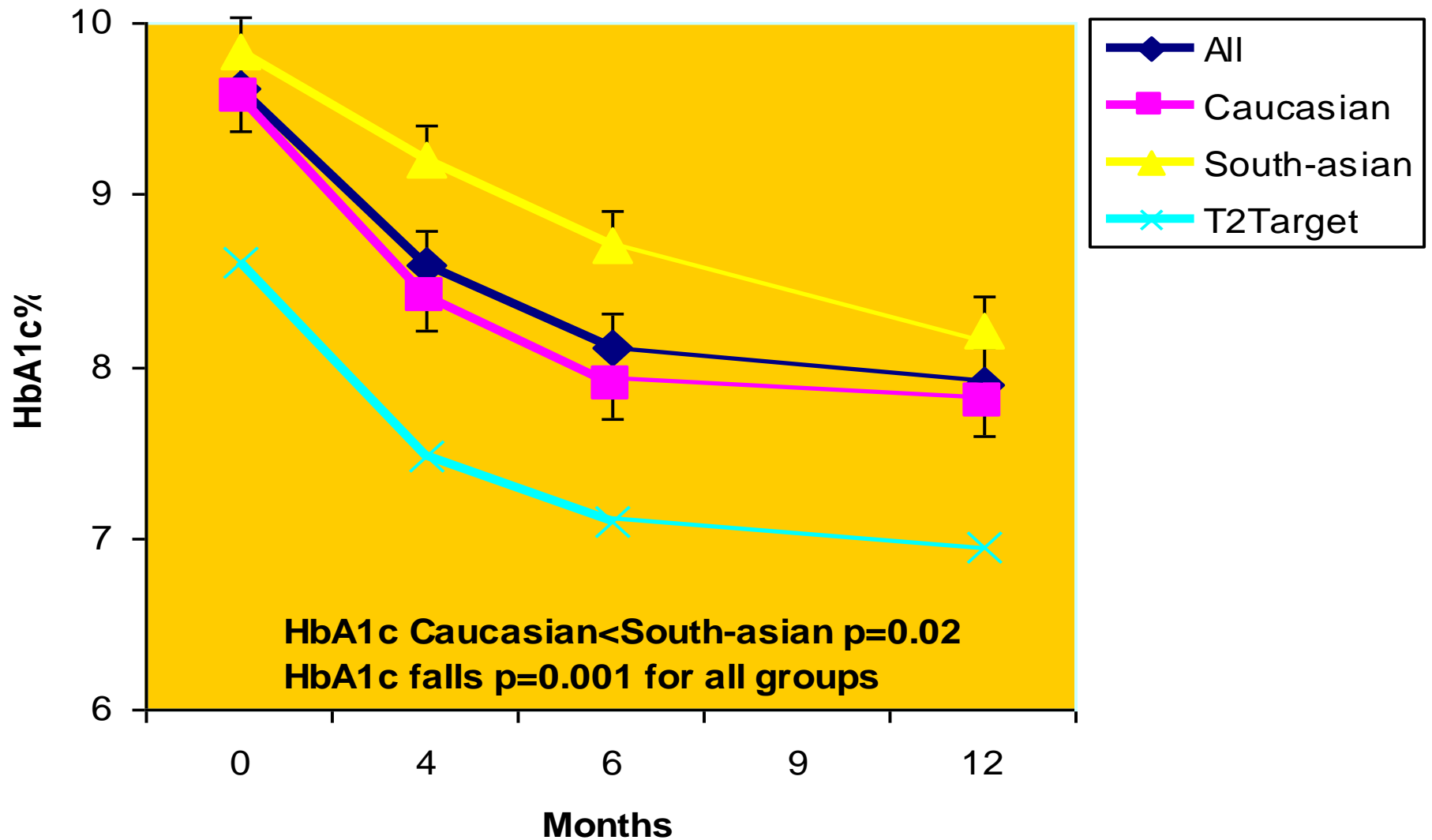
Body mass index



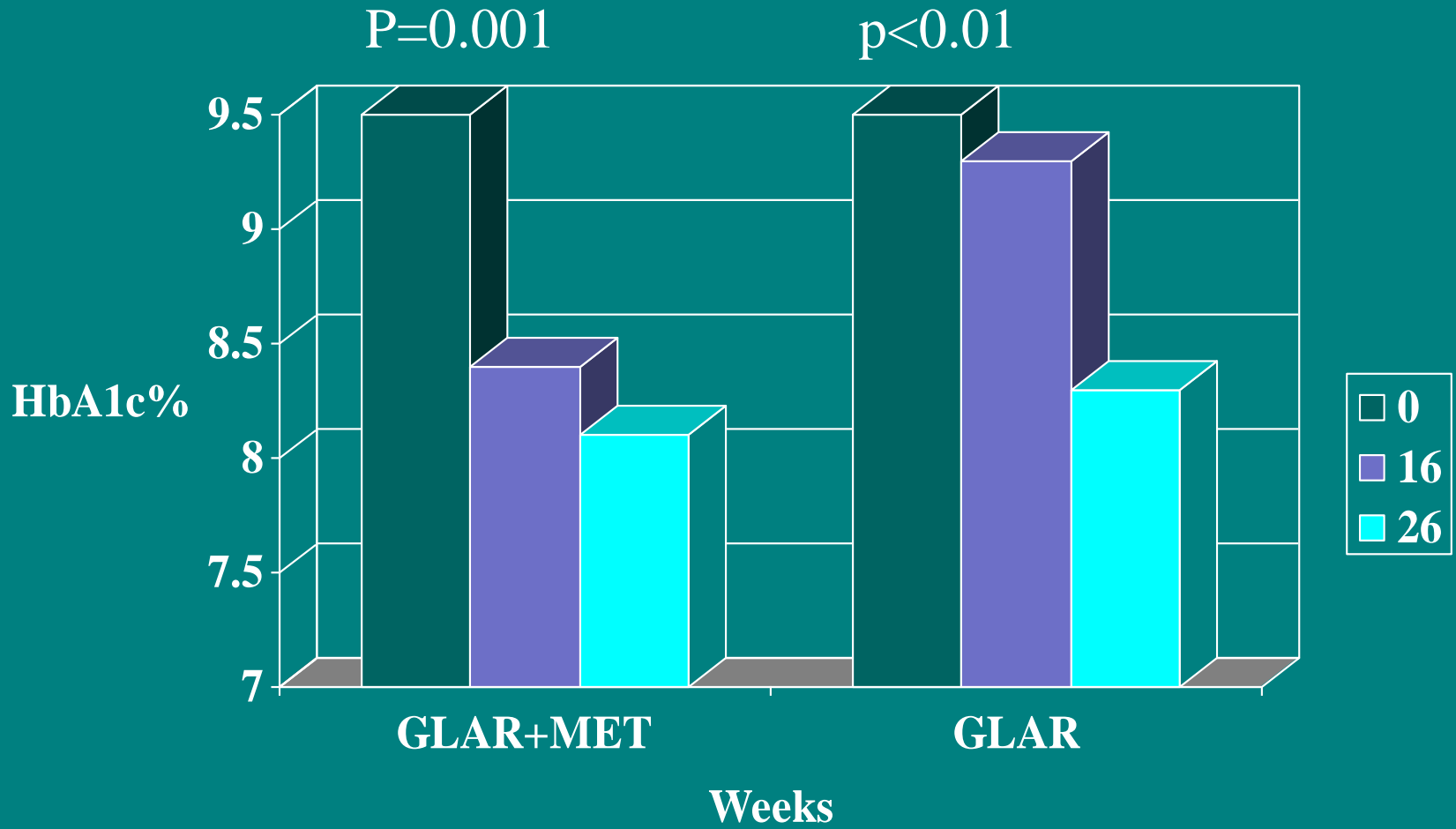
Mild hypoglycaemic episodes



Glycaemic control in T2DM following Glargine treatment



HbA1c



Target achieved?

	HbA1c < 7%	HbA1c < 7.5%
6 months (%)	15%	33%
6 months (n=89)	13	29
12 months (%)	19%	42%
12 months (n=69)	13	26

Achieving target?

Starting HbA1c < 9%

	HbA1c < 7%	HbA1c < 7.5%
12 months (%) n=41	17%	30%

Number of doses of insulin aspart

		<i>n</i>	%
Number of doses of insulin aspart	0	50	56%
	1	17	19%
	2+	22	25%

Conclusions

- Similar falls in blood glucose and HbA1c as TTT/Lanmet
- Similar weight gain and hypoglycaemia as TTT/Lanmet
- However most patients not at target
- Prandial insulin frequently required
- Group starts seem as effective as individual tuition

ABCD Glragine in pregnancy Audit

ABCD

National Glargine (Lantus) use in pregnancy survey.

Audit contact
 Clinic Site
 Lead Consultant
 Contact Telephone
 Contact E mail

Ian Gallen, Wycombe Hospital. E mail ian.gallen@sbucks.nhs.uk, fax 01494425865, tel 01494425349

Subject Demographic Details

Subject identification (Centre Initials and case number eg WH-01)
 Was change to NPH other insulin offered?
 Permission for data collection? If not stop here
 Age (yrs)
 Ethnicity
 Parity
 Gravidity
 Relevant PMH
 Height (m)
 Weight (kg)
 Basal bolus regime
 Bolus Insulin
 Insulin dose (IU) / 24hrs

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Booking Visit

Diabetes Type
 Duration of DM (yrs)
 HbA1c (%)
 Retinopathy present?
 Nephropathy present?
 Smoker
 Folic Acid
 Glargine started
 If Glargine started during pregnancy state reason

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During Pregnancy

Glycaemic control (Mean HbA1c) in
 1st Trimester
 2nd Trimester
 3rd Trimester
 Retinopathy
 Number of hypoglycaemic episodes requiring
 Admission
 3rd party assistance
 glucagon
 Pre-eclampsia (BP> 140/90 **plus** at least ++ proteinuria)
 Hypertension (BP > 140/90 without proteinuria)
 Obstetric Complications (please state)
 Singleton / Twin
 Ultrasound Anomalies reported (please state)
 Trisomy 21 screening

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Outcome

Foetal outcome
 Mode of delivery
 Intrapartum complications
 Insulin dose at birth (IU)
 Gestational Age (weeks)
 Sex of baby
 Foetal weight (kg)

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Neonate

Known Congenital Malformation (please state)
 Apgar score
 Neonatal hypoglycaemia
 RDS
 Polycythaemia
 Hyperbilirubinaemia
 Feeding difficulties
 TTN
 Neonatal death

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Survey so far

- 25 centres have sent data
- 2 have sent 10+ cases each
- 21 replies saying that they don't use glargine in pregnancy
- 20 centres have said they will send data
- 100+ cases
- No data analysis yet
- Please fill in form and send to ian.gallen@sbucks.nhs.uk