Association of Clinical British Diabetologists, Oct 27th 2005

Roles and risks of insulin pump therapy in Type 1 diabetes

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A history

1978: Pickup, Keen, Parsons, Alberti.

Continuous subcutaneous insulin infusion: an approach to achieving normoglycaemia.

Br Med J. 1978 Jan 28;1(6107):204-7.

1979: Tamborlane, Sherwin, Genel, Felig

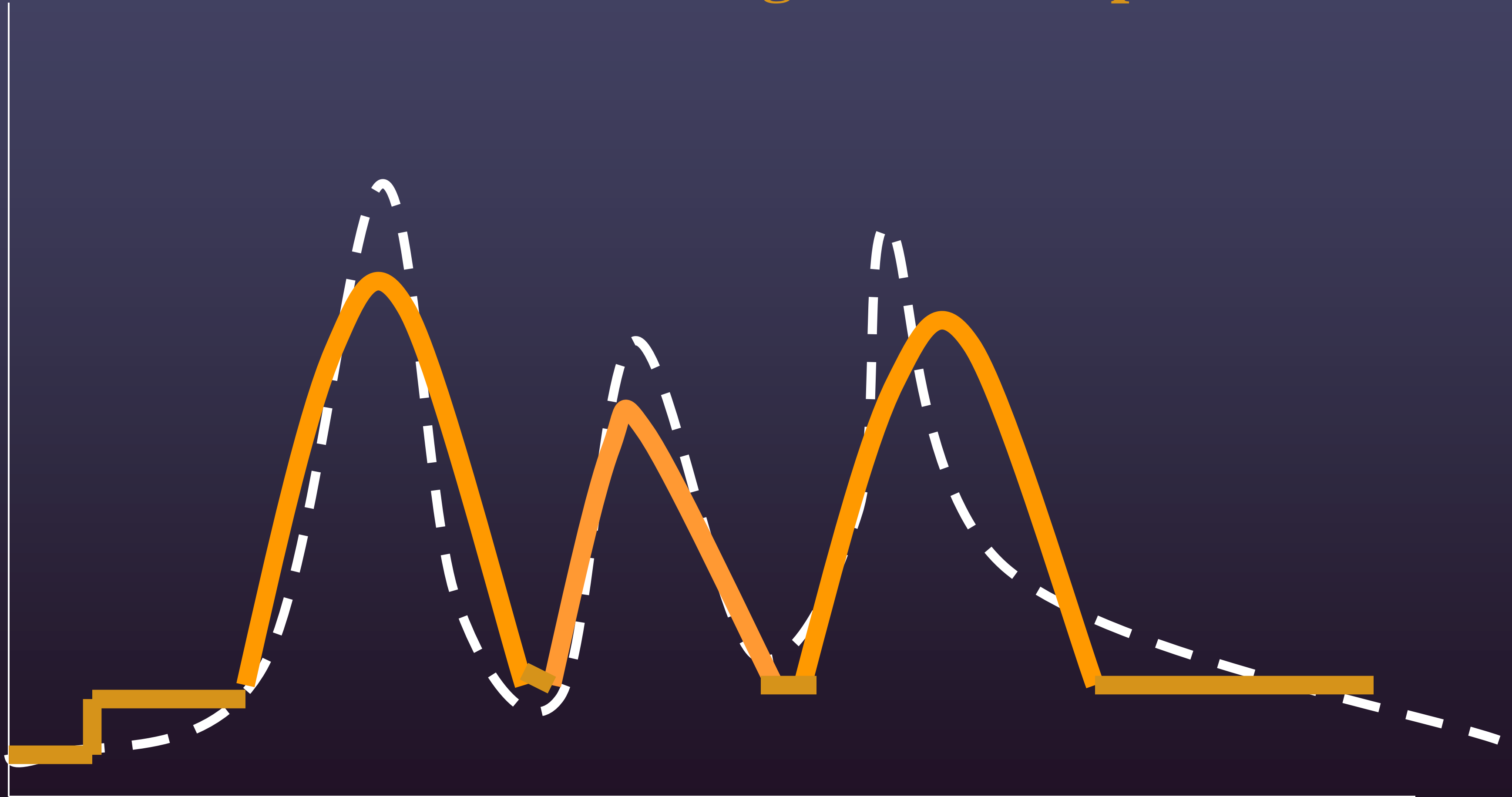
Reduction to normal of plasma glucose in juvenile diabetes by subcutaneous administration of insulin with a portable infusion pump

N Engl J Med. 1979 Mar 15;300:573-8.

PUMP
PAL 1
BOLUS
FOR USE ONLY
UNDER SUPERVISION
OF A PHYSICIAN
506
SEL
ACT

Insulin replacement

CSII with Humalog or NovoRapid



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1983: Boulton, Knight, Drury, Ward

Diabetic ketoacidosis associated with outpatient treatment using continuous subcutaneous insulin infusion.

Postgrad Med J. 1983 Jul;59(693):438-9.

NICE guidance – Feb 2003

Recommended for Type 1 diabetes where:

- MDI has failed (including glargine)
- The patient has commitment and competence

NICE guidance – Feb 2003

- HbA1c < 7.5% (6.5% with complications)
  without disabling hypoglycaemia

- Fall in hypoglycaemia in observational studies
- Requires “trained specialist team”
- OK for adolescents
- Caution in pregnancy
- Not for Type 2
- Requires “trained specialist team”

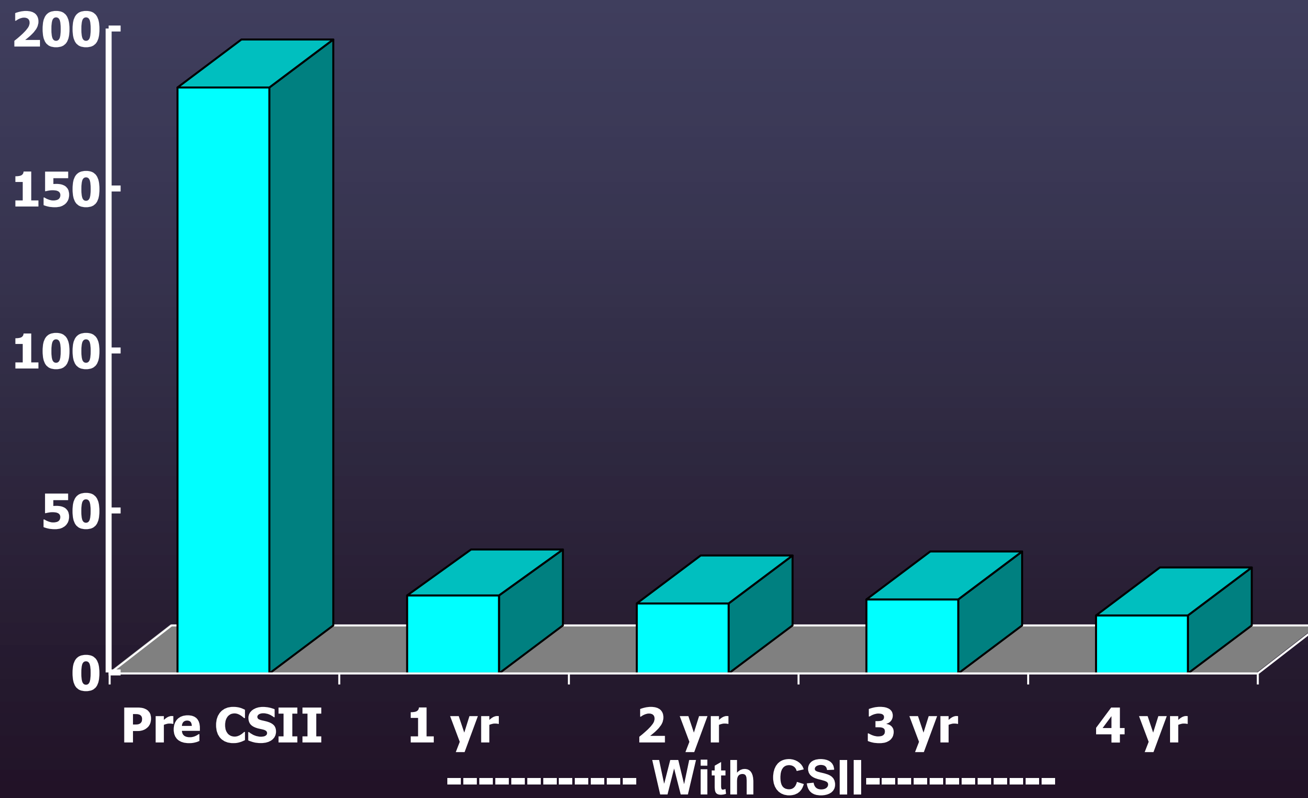
Meta-analysis

- 12 RCTs, 1982 - 2000
- 301 CSII vs 299 injection Rx
- 2.5 – 224 months
- Mean reduction HbA1c 0.51%
- Reduced glycaemic variability
- Risk reduction retinopathy progression 25%
- At lower HbA1c, 0.5 cases per 100 pt yrs

Pickup et al, BMJ, 2002

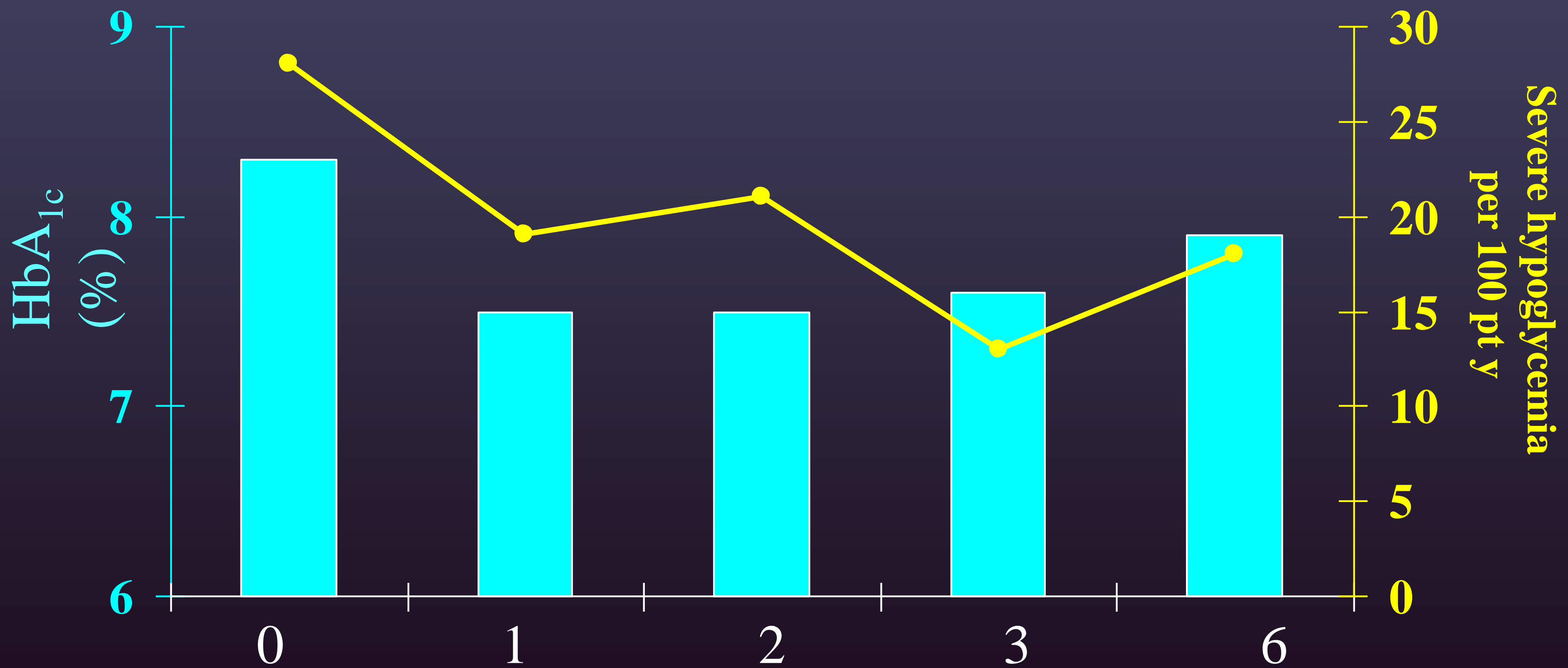
Severe Hypoglycemia Reduced with Pump Therapy

(episodes / 100 pt yrs)



Bode BW:Diabetes Care, 1996; 19:324-327

Effects of educational programme on HbA1c and SH



Jorgens et al, Diabetologia 1993,36

“contraindications”

- Needle phobia
- Extreme concern to hide pump
- Inability to disclose diabetes
- Recurrent DNA
- Unwillingness to calculate meal doses
- Depression or other psychiatric history
- Eating disorder
- Physical or mental disability
- Medical conditions that could be worsened by tight control

Farkas-Hirsch & Hirsch, 1994

LSL guidelines

- Recurrent severe hypoglycaemia *despite optimised medical therapy*
- Demonstration of marked dawn phenomenen, usually after starting
- Pregnancy where HbA1c cannot be reduced below 7% without hypoglycaemia
- Other causes of poor control where 6 month trial therapy in secondary care shows benefit
- Specific eligibility criteria

The King’s Audit

Ian Rodrigues, Helen Reid
Khalida Ismail
Stephanie Amiel

The questions

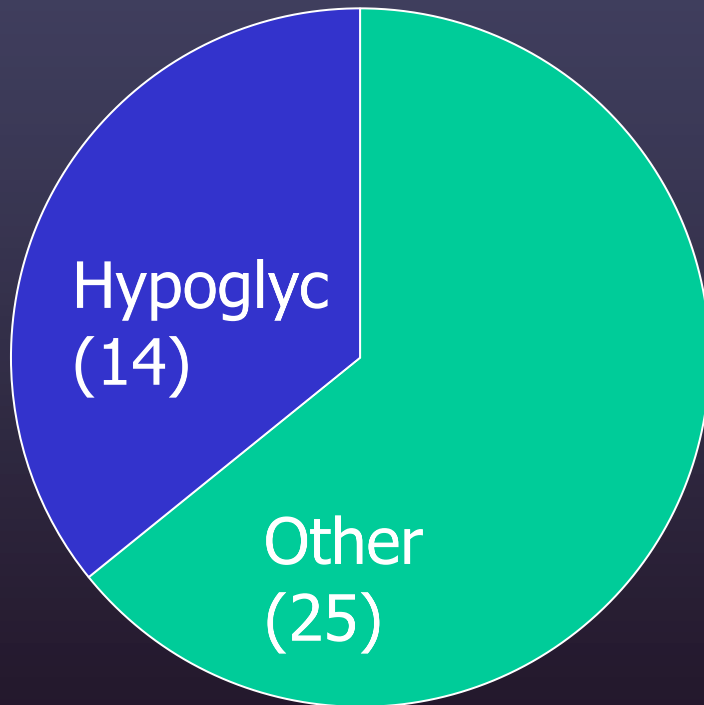
- Are the indications for pump therapy correct?
- Does the application of the classical exclusion criteria remove a useful treatment option from a difficult patient group?

Patient Characteristics

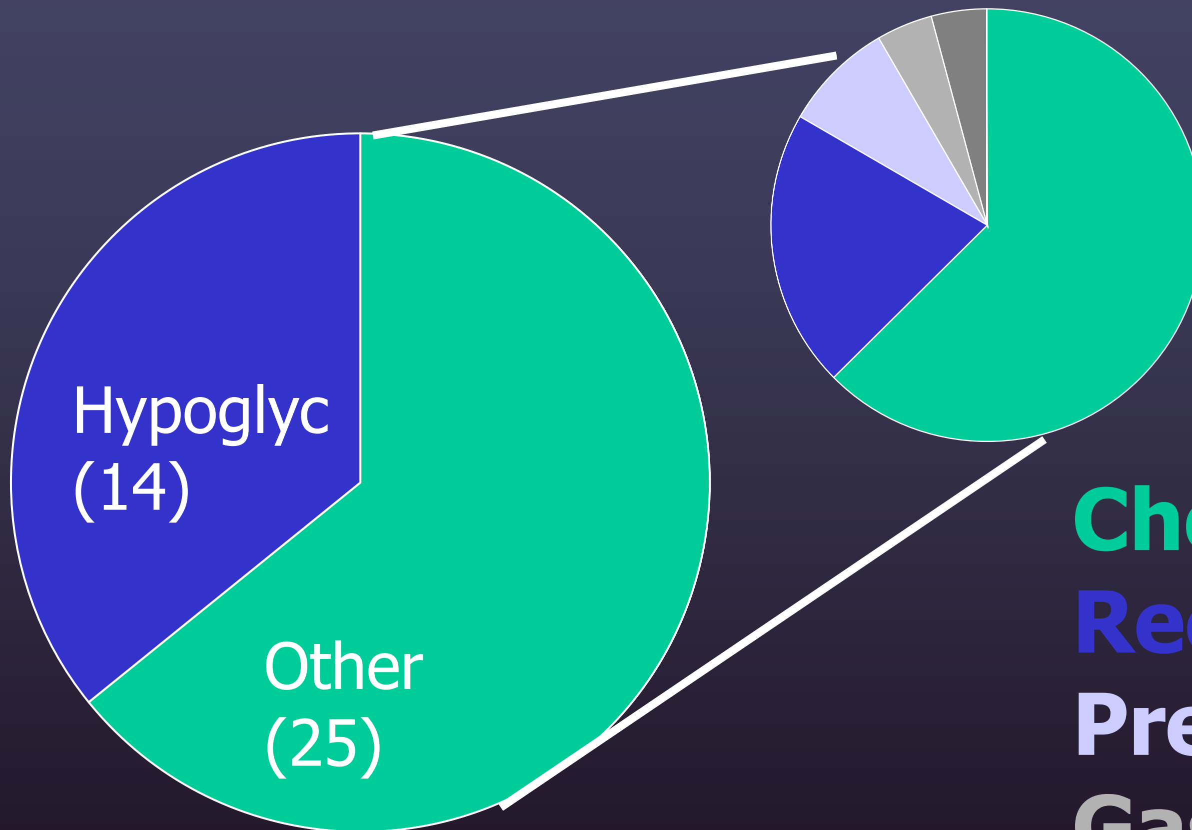
Patients (*n*)	40
Gender (M/F)	25/75
Age (years)	33.2 (12.2; 10-62)
Diabetes duration at CSII start (years)	14.6 (9.8; 2-37)
CSII treatment duration (months)	32.2 (40.2; 1-192)
Body mass index (kg/m^2)	23.9 (4.6; 14-39)
Social Class (1/2/3/4)	20/46/31/3
Ethnicity (% White, British)	77.5

Data are given as mean (SD, range)

The King’s patients

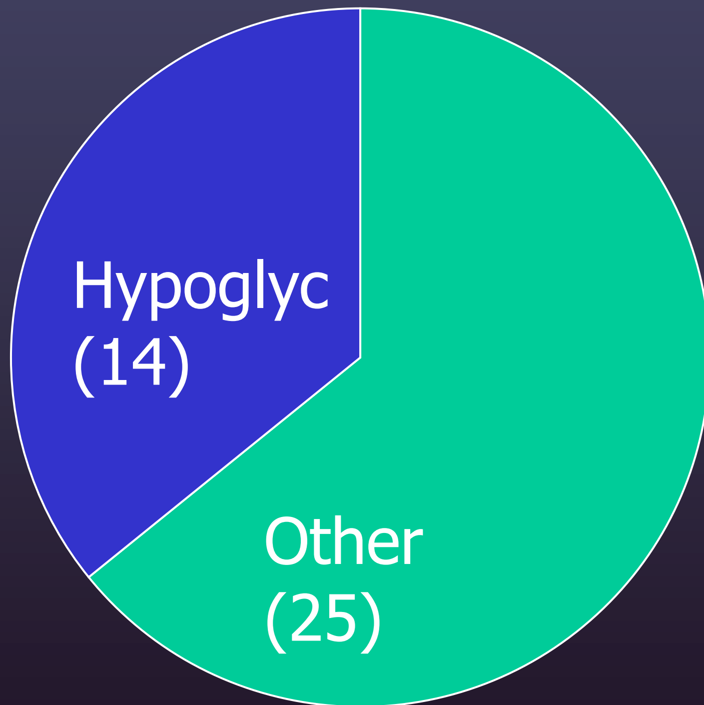


The King’s patients



Choice
Recurrent DKA
Pregancy
Gastroparesis
Erratic life style
Poor control

The King's patients



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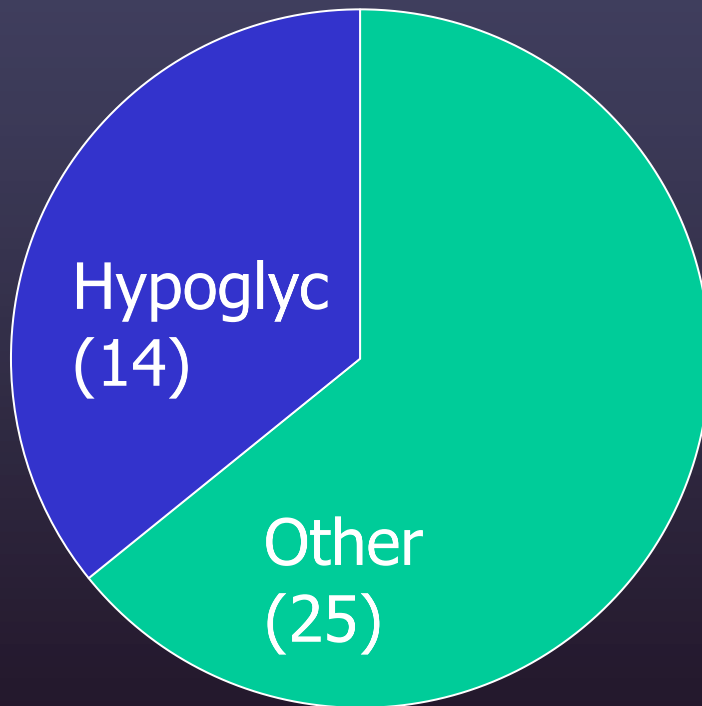
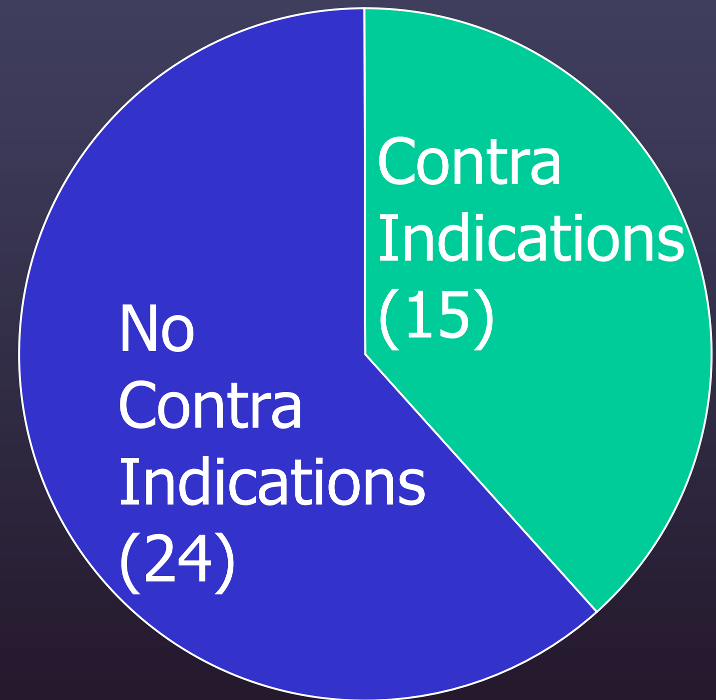
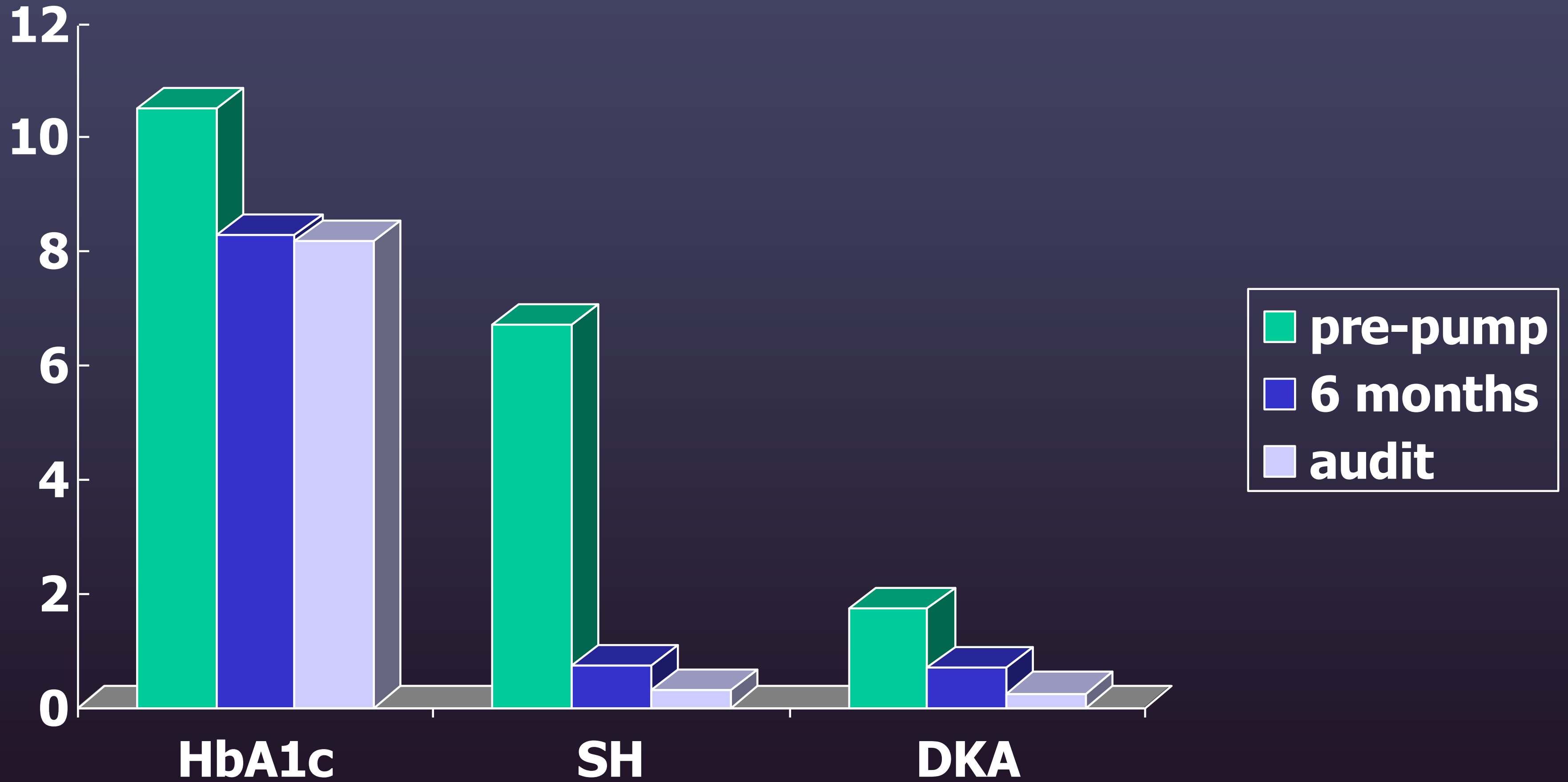




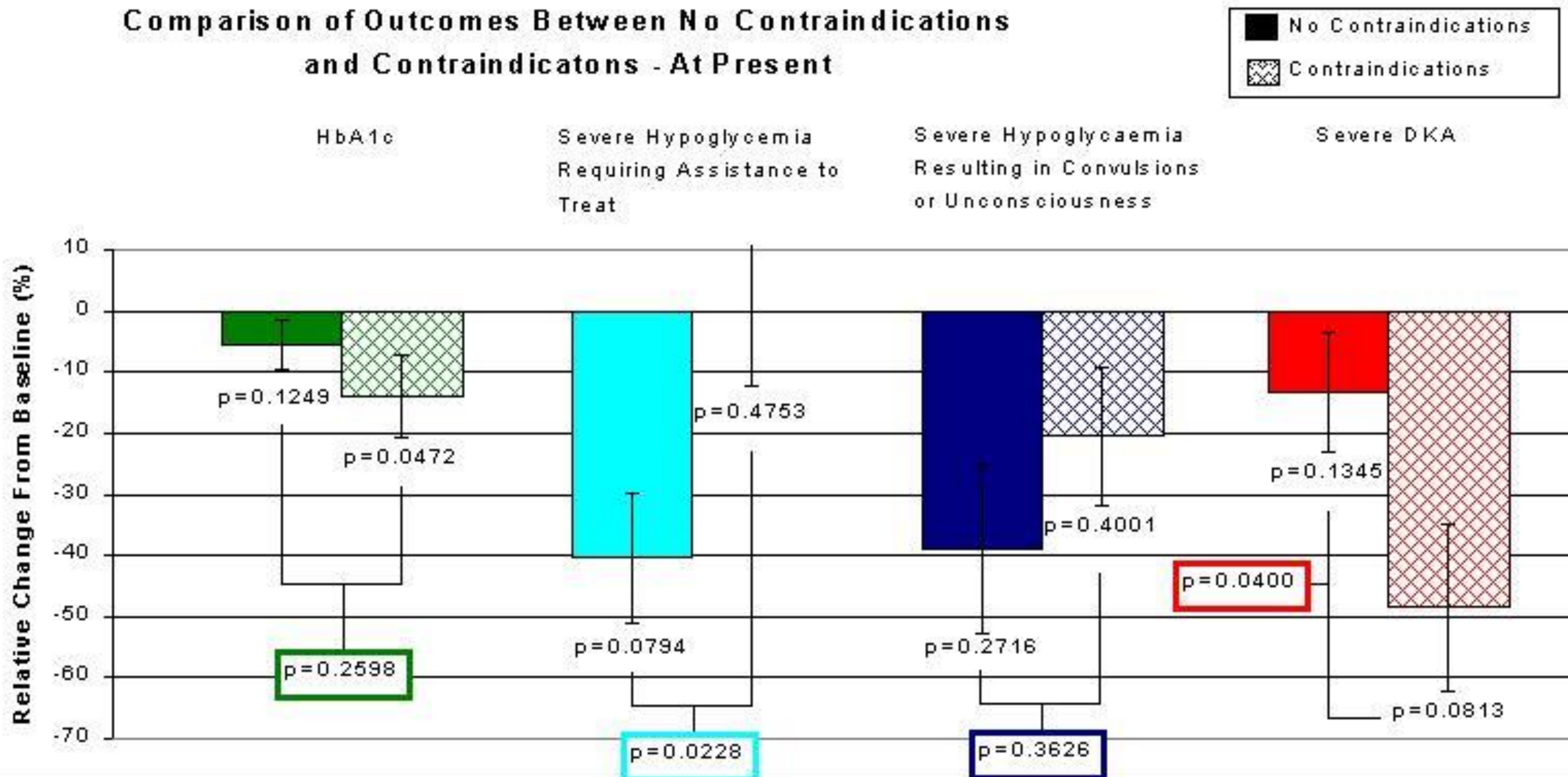
Group data



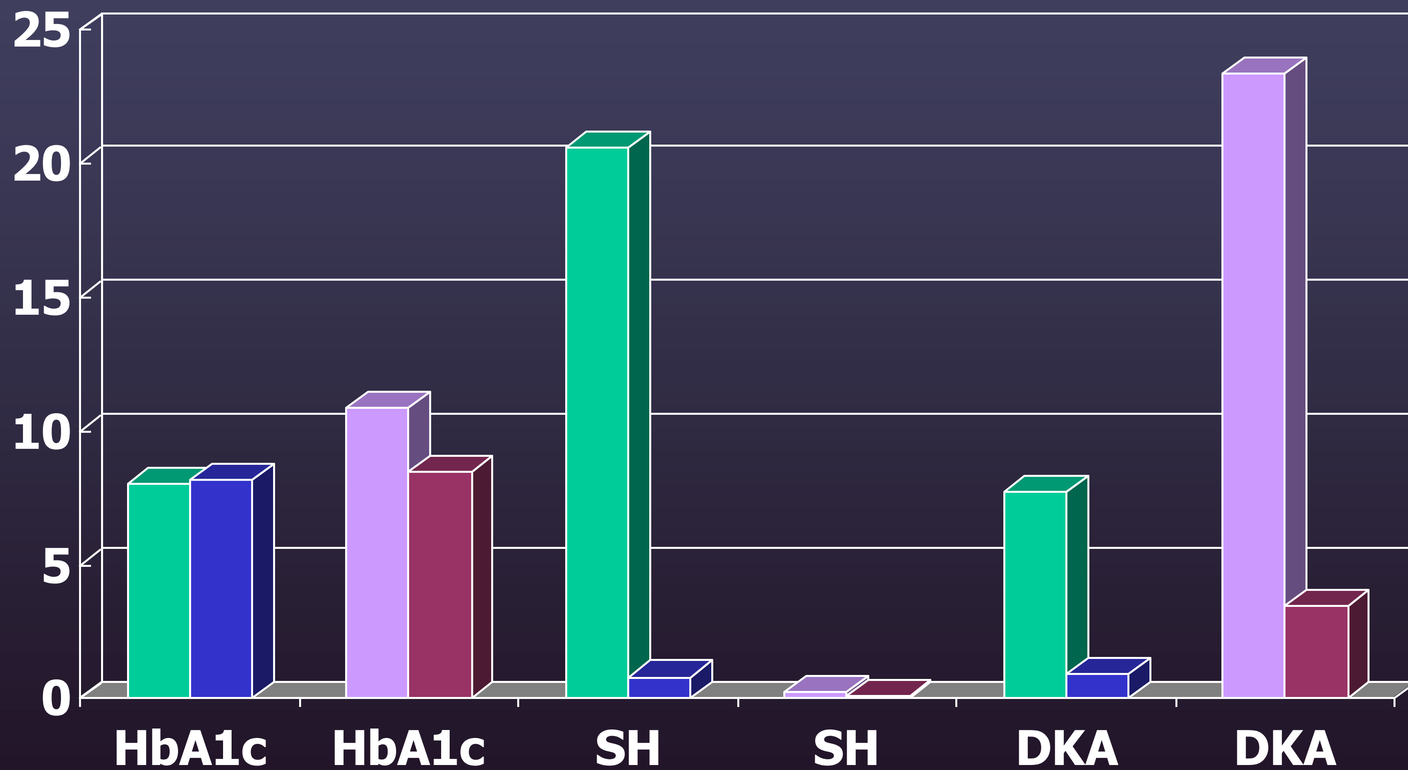
The Dawn Phenomenon

- 50% of patients with evidence of a dawn phenomenon
- Mean step-up in total group = 51.8%
  (± 87.9; Range 0 to 500%)
- Mean step up in those with dawn phenomenon = 99.4%

No Contraindications Vs Contraindications



Problematic hypoglycaemia vs other



Is NICE right?

And what are the costs?

To be eligible patients must:

- Show good understanding of device
- Be able to trouble shoot within 3/12
- Be prepared to carry out 4+ blood tests daily
- Have a history of compiance with MDI
- Be attached to capable clinical service

The Assessment Group

… PUMP (professional) …. 1-2% of type 1 patients …initially…. inevitably rise.

… annual costs to the NHS of £3.5 – 7 million

….£2715 for training a team (physician, DSN, dietitian) … manufacturers ….overestimate, because

1 day – not 3 days – is sufficient to train a physician!

Summary

- The evidence base for CSII shows moderate improvement in HbA1c and glycaemic lability* and for some major improvement in QoL
- In patients with recurrent severe hypoglycaemia it CAN make dramatic improvement
- In a multidisciplinary setting, CSII can help other forms of glycaemic instability

BUT

- CSII should not be considered a terminal therapy
- Patient education critical
- And so is physician experience!
- The calculated costs do not include these

Conclusion

- Pump therapy offers people with type 1 diabetes an additional choice
- It does need to be applied in an experienced setting
- Patients with problematic control need more than just a pump!