

U500 for patients with insulin resistance

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Introduction

Some patients with Type 2 diabetes need very high doses of U 100 insulin needing large volumes and multiple injections. U 500 is a high strength unlicensed insulin which has the potential to reduce the number of injections and may result in better control. The effect on HbA_{1c} and weight has not been compared with U 100.

Methods

Patients with high degree of insulin resistance were selected from the clinic and their treatment was changed from U 100 basal bolus therapy to U 500 TDS sc injections. The effect on HbA_{1c} and weight over 1 year is reported.

Patient group

19 patients from January 2009 to August 2012 were put on U 500 insulin. 11 were still on U500 after 9 months. 4 stopped due to varying degrees of hypoglycaemia and insulin requirement. 2 had bariatric surgery and were off all medications. 2 died for reasons not related to hypoglycaemia or diabetes.

Baseline data before U 500

HbA _{1c}	Range	7.1-15.2 %
	Mean	SD 10.8 2.22%
U100 dose	Range	300-944 units
	Mean	SD 443 146 units
Weight	Range	80.5- 180.2 kg
	Mean	SD 122 25.4 kg

Injection frequency 6-19 per day
Most patients were on Metformin
2 were on Victoza

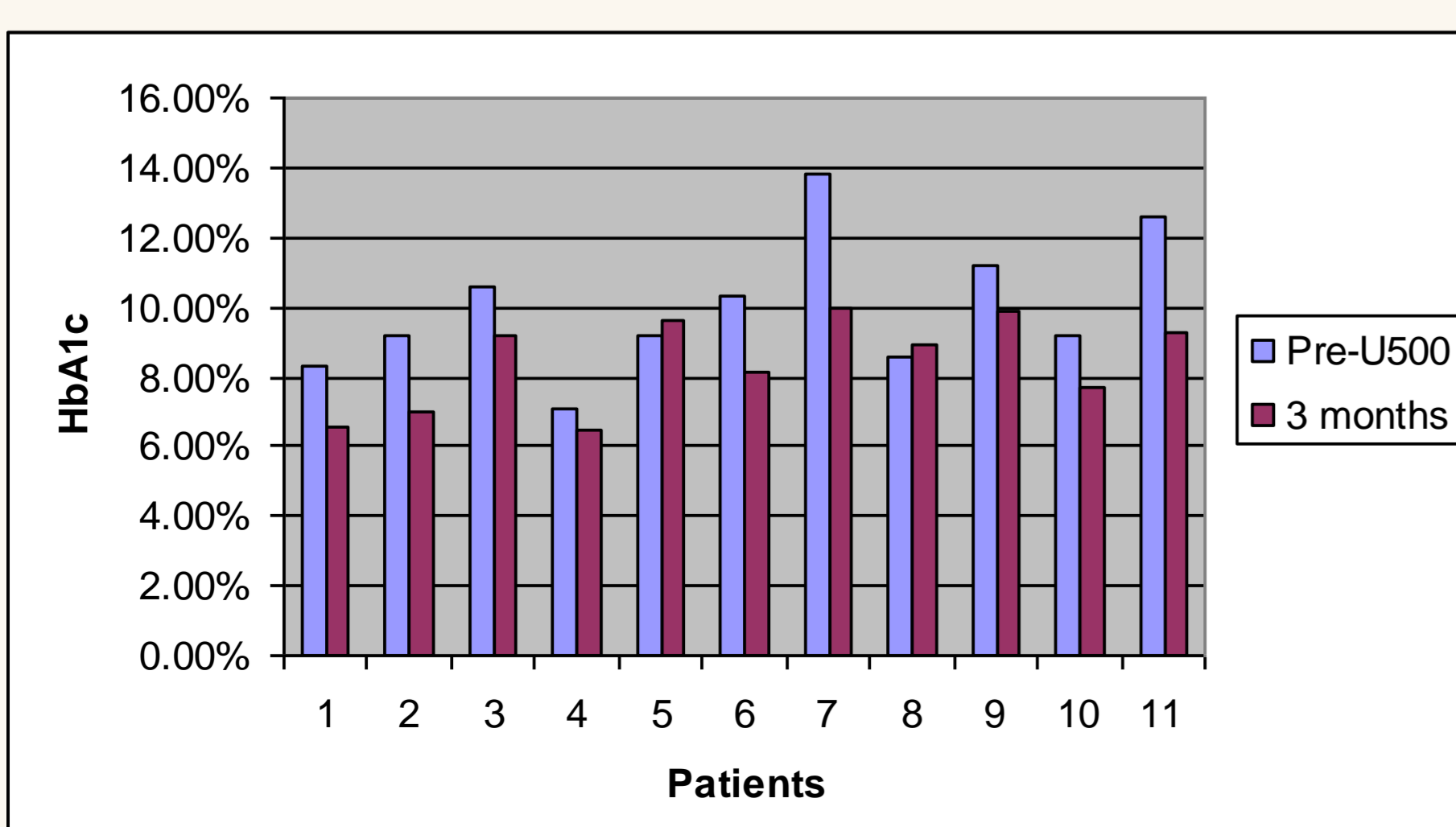
U500 Dose

Total Daily Dose (TDD) in 3 divided doses	Mean	SD	71 marks	20.6
Range	45-120 marks on U 100 insulin syringe			

HbA_{1c} in 3 months

n=11
Mean reduction 1.7 1.1%
N=2 had A_{1c} increase (0.4% and 0.3%)

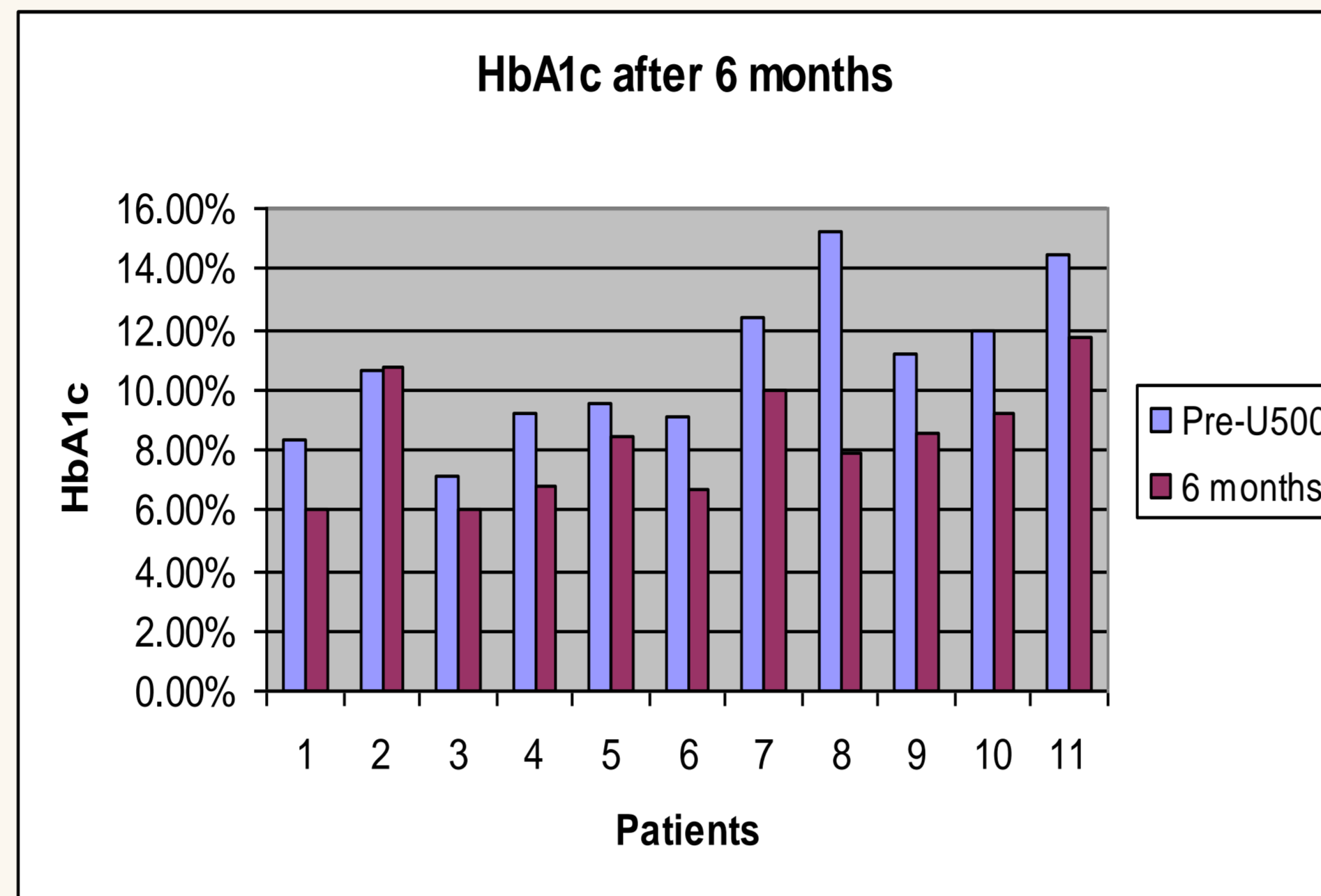
HbA_{1c} in 3 months



HbA_{1c} in 6 months

n=11
Mean reduction 2.47 1.91 %
n=1 had HbA_{1c} increase (0.1%)

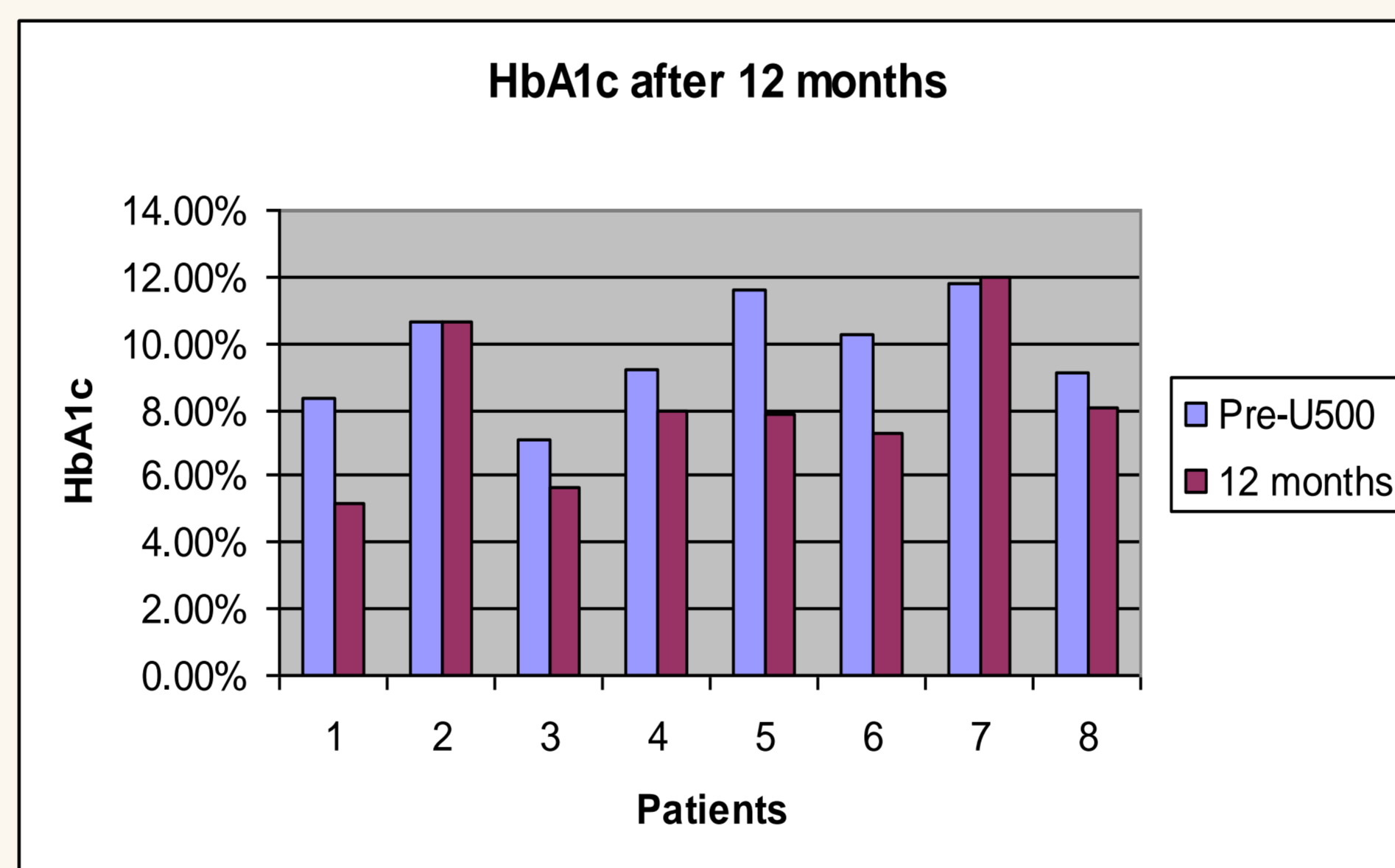
HbA_{1c} in 6 months



HbA_{1c} in 1 year

n=9
Mean reduction = 1.5 2.50
n=1 had increase A_{1c} (0.2%)
n=1 A_{1c} unchanged from start

HbA_{1c} in one year



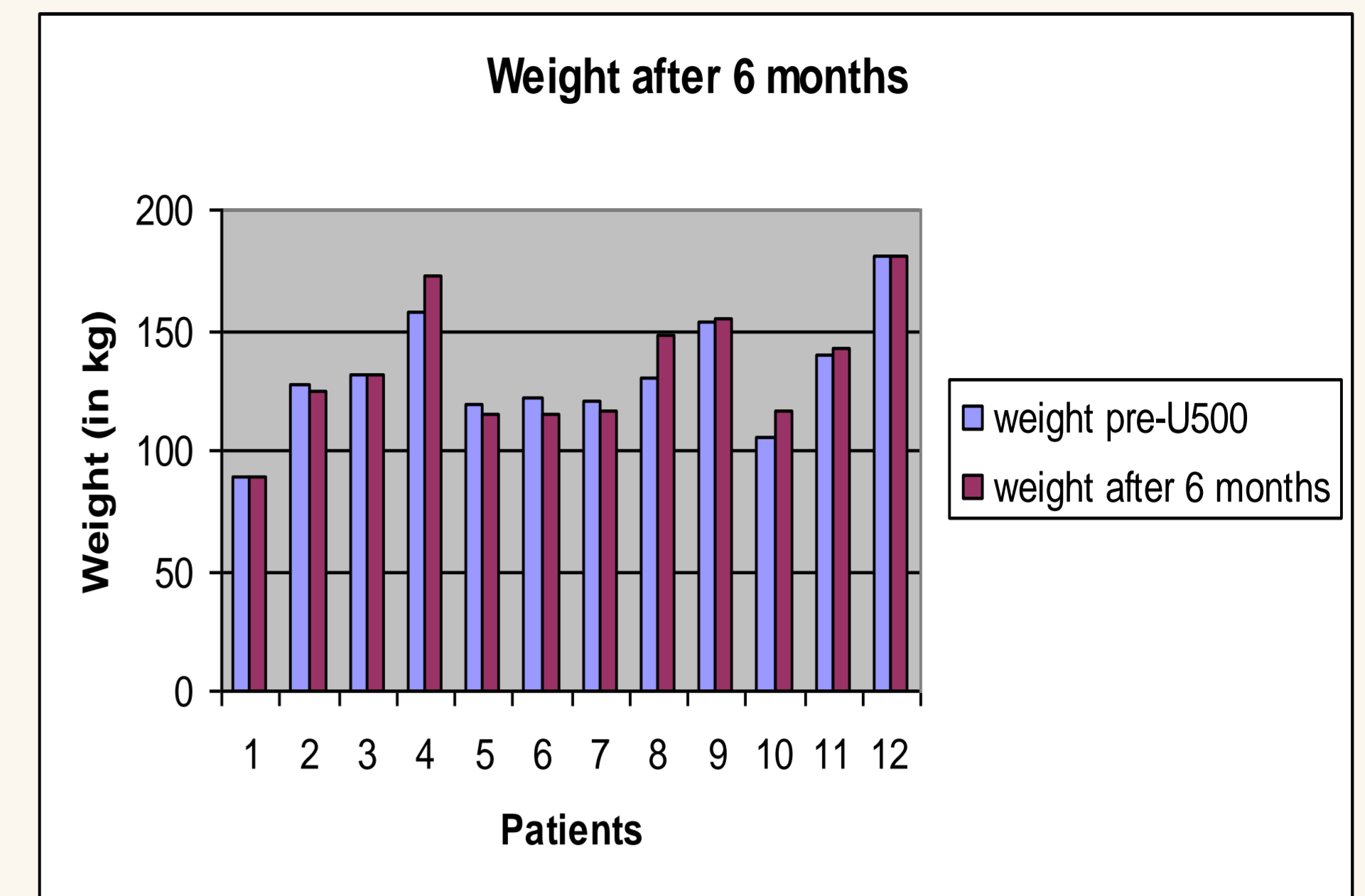
Change in insulin dose

n=15
Mean dose at start: 71 marks TDD
Mean dose at the end: 89 marks TDD
n=4 needed dose reduction (-14, -45, -36, -24)
n=11 needed increased dose
Average dose increase= 36 marks

Change in weight (6 months)

Mean weight at start: 122 kg
Mean weight after 6 months: 133.8 26.5 kg
N=7 weight gain with mean 6.8 kg, range (0.4 kg-17.3 kg)
N=5 weight loss with mean 5 kg, range 0.8 kg -6.65 kg

Weight after 6 months



Rationale for U 500

Severe insulin resistance
High frequency of injection
Patients complaining of bruises, sore/painful injections, running out of sites to inject
Cost

Cost

ESHT- £37,407
Average pen use for U100- 1.67 pens
Cost of pens/cartridge- £9
Cost of 20 ml vial U500-£254.47
Cost of Lantus/Novorapid combo-£15.35 per day
Cost of Levemir/Novorapid combo-£14.38 per day
Average cost of basal bolus analogue per day- £14.87 (PCT)
Average U500 cost/day-£11.43 (ESHT)
Calculated cost for 20 patients per year
U100 analogue- £108,514.50
U500-£83,439.00
Difference-£25,075.50

How about Human Insulins?

Cost of NPH- £5 per pen/cartridge
Cost of Human SA- £3.8 per pen
Total cost per day-£7.35
Total cost per year per patient-£2682.75
Total cost per year for 20 patients- £53,655
Cost difference for 20 patients
U500 vs. Human insulins (U100)- £29,784
Human Insulins vs. Analogues- £54,859.50

Summary

U500 use for severely insulin resistant patients can lead to:

HbA_{1c} improvement
Weight gain
Hypos: 31% of patients (small sample)
Financial savings
Patient satisfaction