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 HbA1c 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 HbA1c 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
HbA1c
- Range: 7.1-15.2 %
- Mean: 10.8 ± 2.22%
U100 dose
- Range: 300-944 units
- Mean: 443 ± 146 units
Weight
- Range: 80.5-180.2 kg
- Mean: 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: 71 marks 20.6
- Range: 45-120 marks on U 100 insulin syringe

HbA1c in 3 months
n=11
Mean reduction: 1.7 % 1.1%
N=2 had A1c increase (0.4% and 0.3%)

HbA1c in 6 months
n=11
Mean reduction 2.47 1.91 %
n=1 had HbA1c increase (0.1%)

HbA1c in 1 year
n=9
Mean reduction = 1.5 2.50
n=1 had increase A1c (0.2%)
n=1 A1c unchanged from start

HbA1c in one year
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 insulin dose
HbA1c after 12 months

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

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
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 Levens/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:
HbA1c improvement
Weight gain
Hypo: 31% of patients (small sample)
Financial savings
Patient satisfaction