The long-term insulin management with premixed insulin in neonates and infants with diabetes

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BACKGROUND
- To describe a new therapy protocol for the long-term insulin management in neonates and infants with diabetes.acts on neonatal body weight gain.

MATERIALS AND METHODS
- Male and female infants younger than 36 months, who had ND or T1D, were enrolled the study.
- All the infants were fed with three hours intervals.
- Before six months old, the infants were allowed to take breast milk or formula as much as they wanted at each feeding time.
- Three main meals and three snacks were organised.
- The patients were started insulin therapy with 0.6 U/kg/day divided equally into four doses.
- Severe hypoglycemia was defined as symptoms (semiconscious or unconscious, coma, death); plasma glucose level <70 mg/dL (3.9 mmol/L) or any asymptomatic blood glucose meter reading <70 mg/dL (3.9 mmol/L), or any asymptomatic blood glucose meter reading <70 mg/dL (3.9 mmol/L), and which was handled by the parents.
- Severe hypoglycemia was defined as symptoms (semiconscious or unconscious, coma, convulsions) that might require parenteral therapy (glucagon or i.v. glucose) and associated with a blood glucose meter reading <70 mg/dL (3.9 mmol/L) and requiring third-party assistance.
- A glucose level higher than 180 for fasting and 200 mg/dL for post prandial measurement was considered hyperglycemia.
- Antropometric measurements including body weight and height were performed at the diagnosis and every visit.
- The primary endpoints included 9-point plasma glucose profiles (fasting and post prandial at insulin dose time and at 3 AM) and sufficient weight gain. Secondary efficacy endpoint was change in HbA1c at the last visit.

RESULTS
- Of the 11 patients who entered the study, five patients were diagnosed as ND. The other six patients had T1D.
- Case 4 was consulted by another medical centre while he was 2 months old because his blood sugar levels showed rapid fluctuations under insulin pump therapy.
- The mean diagnosis ages of the patients with ND and T1D were 59.4±101.1 day and 19.1±4 month, respectively.
- None of the patients with ND had ketoacidosis, while four patients with T1D presented with ketoacidosis.
- At the diagnosis, the mean blood glucose level of the patients was 460.3±195.4 mg/dl.
- The mean HbA1c level of the patients with T1D at diagnosis was 10.4±0.9.
- The patients with ND had not antibodies for T1D.
- Four patients had mutant genes for ND, while one patient (Case 5) had no genetic mutation.

CONCLUSION
- We described a specific therapy protocol for long-term insulin management of neonates and infants with diabetes.
- The findings of this study suggest that the method is effective, convenient, and successful.
- However, prospective studies including a large number of the subjects are required.