Use of InsuPad in Daily Practice: Results from a Randomized Controlled Real-World Study

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Introduction

The InsuPad device has been developed to enhance insulin absorption by standardized warming of the injection site after insulin administration. The primary objective of this prospective controlled study is to investigate the impact of InsuPad use on prandial rapid acting insulin dose and glycemic control when studied under real world conditions.

Tab.1: Insulin Doses

Prandial insulin				
Control	66.1±32.1	70.8±38.0	+8.1 %,	p<0.05
InsuPad	69.6±43.1	55.0±33.9	-19.4 %	p<0.001
Basal insulin				
Control	46.8±20.2	47.4±19.6	+2.9 %	n.s.
InsuPad	50.3±32.1	52.4±36.0	+3.4 %,	p<0.05
Total daily insulin dose				
Control	109.6±42.9	113.6±46.8	+3.7 %	p<0.001
InsuPad	114.0±66.7	104.2±63.3	-8.6 %	p<0.001

Methods

This study was performed with 145 patients (51 female, 94 male, 13 type 1 and 132 type 2 patients, age: 61.6±8.4 yrs., disease duration: 16.6±7.2 yrs., HbA1c: 7.19±0.50 %, body weight: 105.7±18.6 kg). All patients were treated with multiple daily injections with insulin glargine and any of the existing short acting insulin analogs (aspart, glulisine, lispro). After a run-in treatment optimization and basal insulin stabilization period of up to 4 weeks, the patients were randomized to continue therapy for three months without (Control, n = 72) or with InsuPad (n = 73 patients). Only 3 visits at the site (screening, baseline, endpoint) were performed to ensure real-world conditions. Observation parameters included HbA1c, insulin dose, frequency of hypoglycemia, and body weight.

Fig.1.: Target HbA1c values reached at endpoint

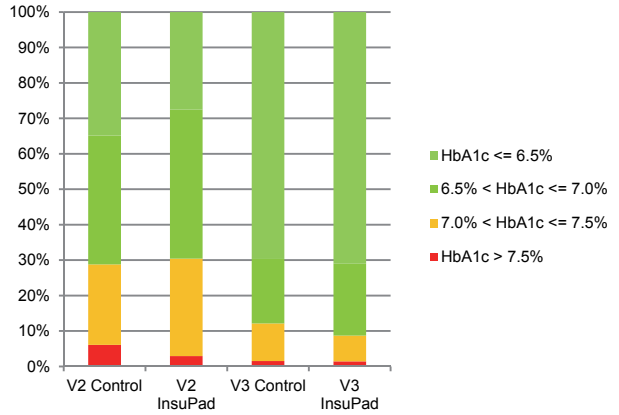
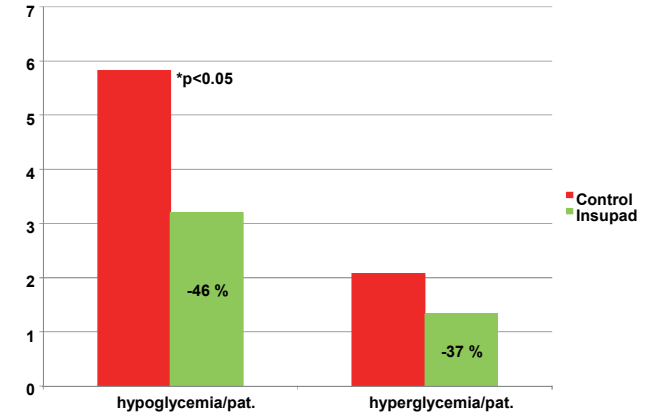


Fig.2.: Frequency of hypoglycemic and hyperglycemic events



Results

During the run-in period, HbA1c decreased in the whole group from 7.2±0.5 % to 6.8±0.5 % (p<0.001), and further improved in both arms until study end (Control group: 6.3±0.5 % InsuPad: 6.2±0.5 %; both p<0.001 vs. baseline, n.s. between the groups). To achieve this glycemic control, patients in the control group needed an increase in the daily prandial insulin dose from baseline by 8 % (from 66±32 U to 71±38 U, p<0.05) with stable basal insulin requirements (47±20 U vs. 47±20 U, n.s.). Patients in the InsuPad group required significantly less prandial insulin to reach these HbA1c results (70±43 U to 55±34 U; -19 %, p<0.001) and a slight increase in the basal insulin dose (from 50±32 U to 52±36 U, p<0.05). In consequence, total daily insulin dose increased in the control group (+3.7 %) and decreased with InsuPad (-8.6 %, p<0.001 between the groups, Fig. 1). The number of hypoglycemic events (blood glucose readings <63 mg/dL) during the observation period was significantly higher in the control group (6.2±9.9/patient) than in the InsuPad group (3.4±4.9/patient, p<0.05).

Conclusions

In conclusion, use of the InsuPad device for three months resulted in a significant lower frequency of hypoglycemic events and a significant reduction in insulin requirements as compared to the Control group under real-world conditions. InsuPad may be useful to achieve HbA1c targets with a safer and more efficient basal bolus therapy in insulin-treated patients with type 1 and type 2 diabetes.

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