



Holding The Horses Of Insulin Pump Infusion: Usage And Effectiveness Of The Low Glucose Suspend Feature During Fasting In Ramadan Among Adolescents With Type 1 Diabetes Mellitus To Prevent Hypoglycemia

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INTRODUCTION

❖ Ramadan is a lunar-based month, and its duration varies between 29 and 30 days. Muslims who fast during Ramadan must abstain from eating, drinking and use of oral medications from predawn to after sunset; however, there are no restrictions on food or fluid intake between sunset and dawn. Although the sick are exempted, many patients, including those with diabetes, choose to go ahead with fasting, often for social and cultural as well as religious reasons. Severe hypoglycemic episodes during the daytime of Ramadan fasting is the most feared complication. Sensor-augmented pump therapy with insulin in combination with automatic insulin shutoff (low glucose suspend [LGS]) can be used to reduce hypoglycemia.

AIM OF THE WORK

❖ This study was primarily designed to determine whether the frequency and degree of hypoglycemic episodes could be reduced through the use of insulin pump therapy with LGS feature using a hypoglycemia alert as well as its efficacy and safety during fasting.

SUBJECTS AND METHODS

❖ **Subjects:** The present study included thirty-seven patients (23 males and 14 females) type 1 diabetic adolescents who wished to fast the month of Ramadan between 9th of July and 7th of August 2013 (30 days). All used Paradigm® Veo™ system (Medtronic Minimed, Northridge, CA, USA) and administering short-acting insulin analogue. **Inclusion criteria:** (1) Adolescents on insulin pump therapy for at least six months, (2) Patients with good metabolic control, (3) Those who attended the whole education sessions two months before fasting and committed to follow up the given instructions.

Exclusion criteria were: (1) Patients who were pregnant or planning to get pregnant during the study, (2) Those with recent history of (DKA), (3) Patients who had diabetic microvascular complications, (4) Those who had more than one episode of severe hypoglycemia; or had visited the emergency room for symptoms related to uncontrolled diabetes in the previous 6 months.

❖ **Methods:** All subjects underwent the following:

• **Detailed Questionnaire:** Complete history taking including their age, diabetes duration, complications, insulin doses (Total, basal and boluses), days fasted in Ramadan, frequency of significant hypoglycemia, hyperglycemia, attacks of DKA, and rate of hospitalization.

• **Pre-Ramadan medical assessments, education and instructions:**

Prior to Ramadan, patients received adequate training and education, particularly with respect to self-management of diabetes related emergency, checking their infusion rates and do frequent home blood glucose monitoring.

• **Breaking the fast:** All patients were instructed that they must always and immediately end their fast if blood glucose reaches <70 mg/dl or if they had symptomatic hypoglycemia. Also to have a regular balanced diet and do not perform vigorous exercise. They were also instructed to measure ketone concentrations using a urine dipstick with every BG concentration >300 mg/dL.

• **Investigations:** Mean random blood sugar, mean pre and post meal blood glucose levels, HbA_{1c} values were measured.

Patients were randomized either to continue using the insulin pump (n=16) or to use the sensor-augmented pump with low-glucose suspension activation (n=21) and data were processed using CareLink® system Clinical Therapy Management.

RESULTS

• Patients' mean age was 15.6±3.3 years, duration of diabetes was 4.9±4.2 years, and used pump therapy for 1.8±1.1 years.

• A total of 2,314 LGS alerts occurred, and 70% began in the afternoon between 2pm - 5pm followed by 12-4 pm timings (Fig.1).

• The mean duration of LGS events was 26.55 min, 38% lasted for <5 min, and 7% lasted for 120 min (Fig.2). Among these episodes, the mean sensor glucose was 61.3 ± 9.4 mg/dl at LGS activation, rose to 110.7 ± 34.6 mg/dl by the end of the LGS episode (when insulin delivery was automatically resumed), and was 163.33 ± 42.1 mg/dl at 240 min.

• The frequency of hypoglycemic events in patients on insulin pump was less in those with LGS feature than without at day time (P<0.001-Fig (3)).

• Compared to the second group, LGS usage significantly reduced the AUC<70 and <60 mg/dl (p = 0.001-Fig(4)) and >250 mg/dl (p = 0.03).

• None of the LGS group broke their fast vs. eight in the second group (p = 0.02), HbA_{1c} levels did not change before or after Ramadan (p=0.3).

• Sensor wear time(%) was 83.2 ± 8.36 and sensor life was 4.2 ± 1.72 days.

• No episodes of severe hypoglycemia or DKA were observed in both.

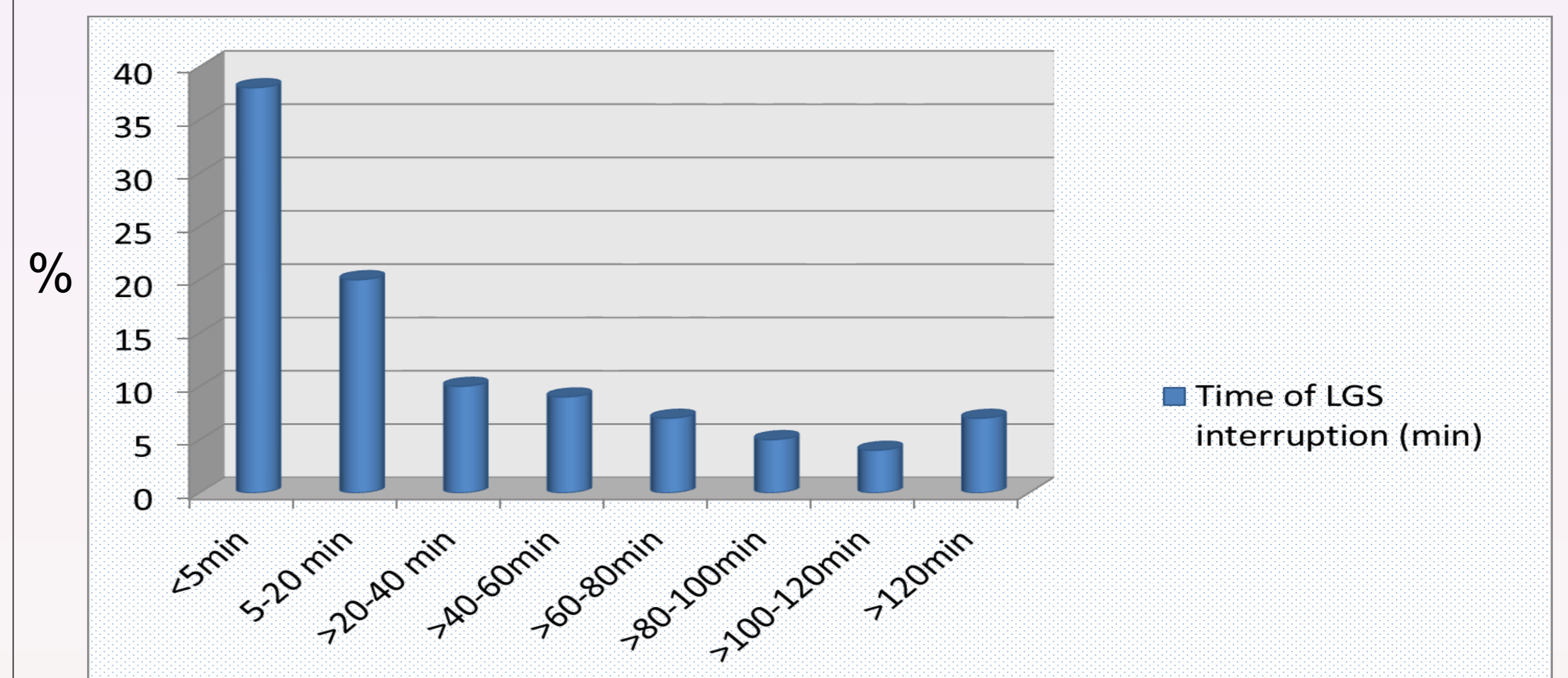


Figure (2): Low Glucose suspend time interval

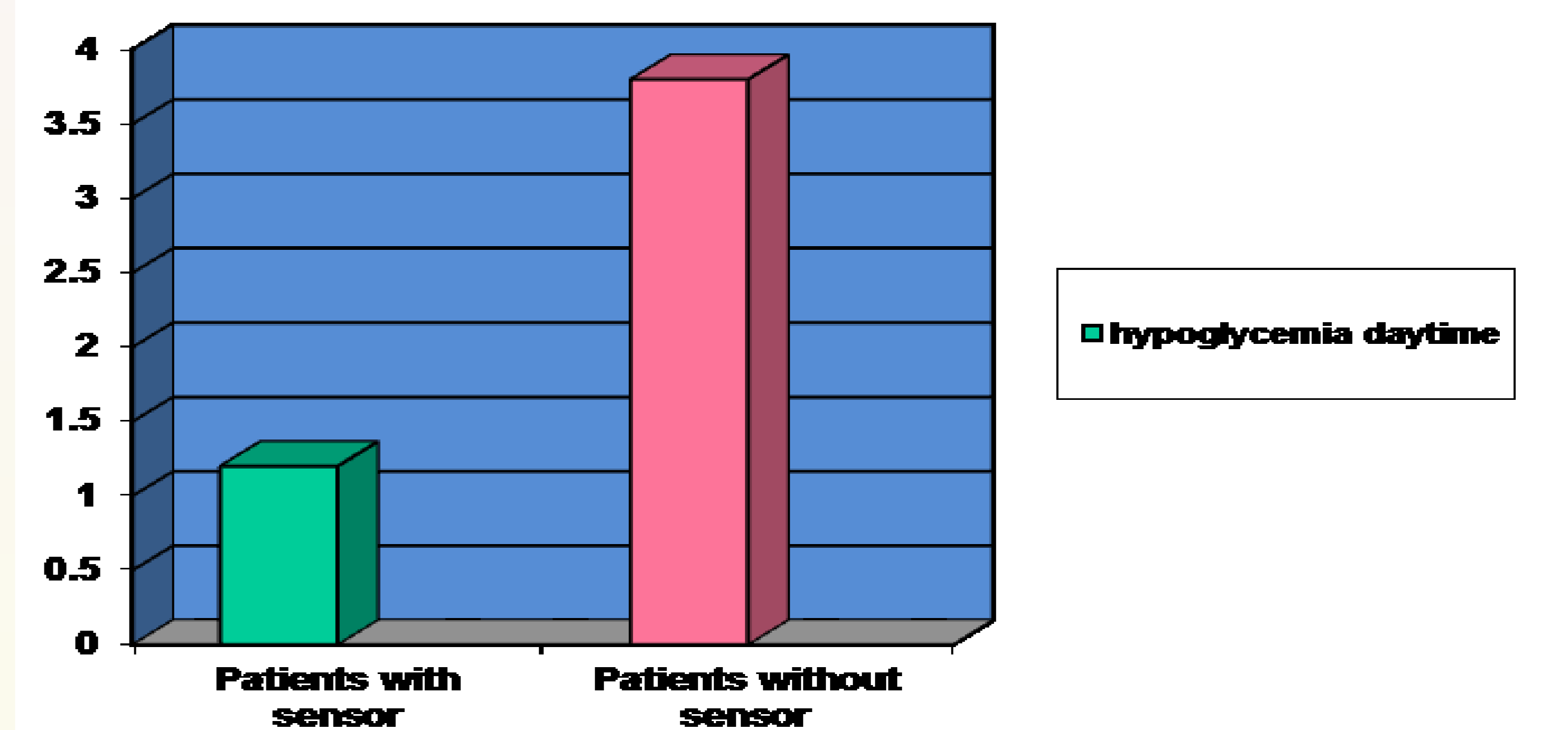
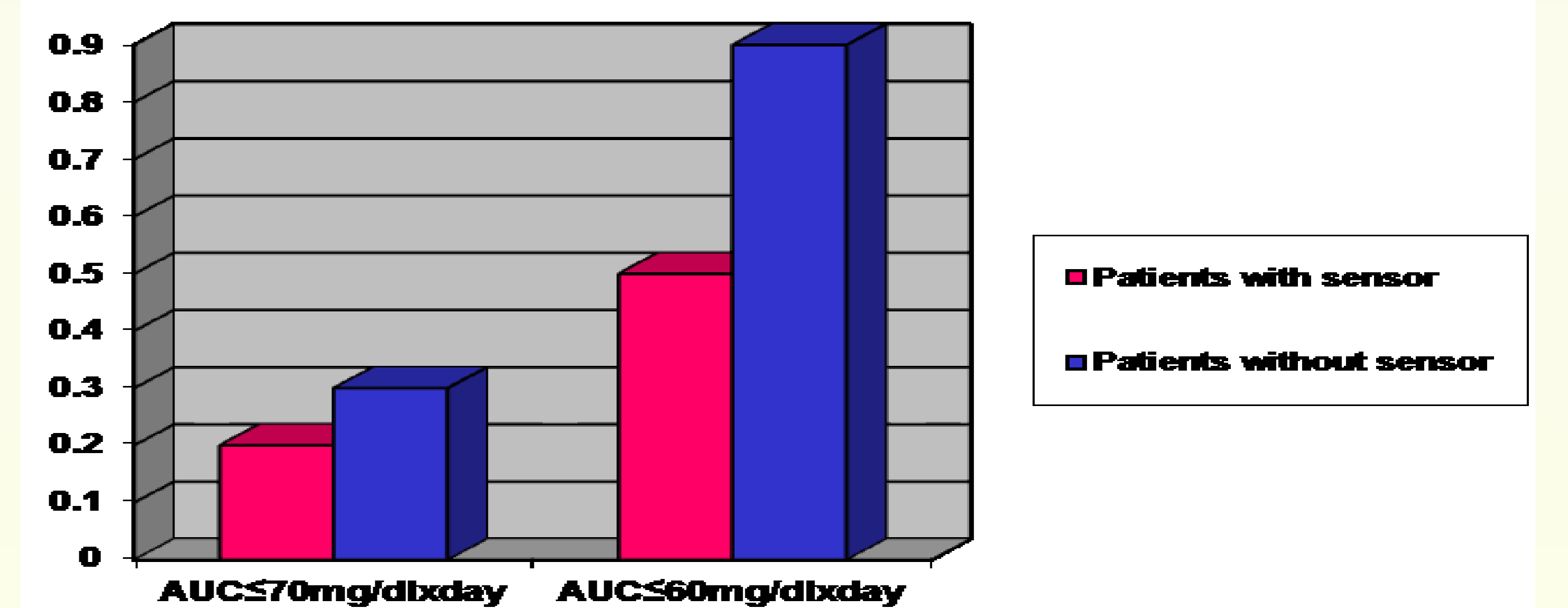


Figure (3): Comparison between frequency of Hypoglycemic events in patients on insulin pump with and without (LGS) at day time (P<0.001)

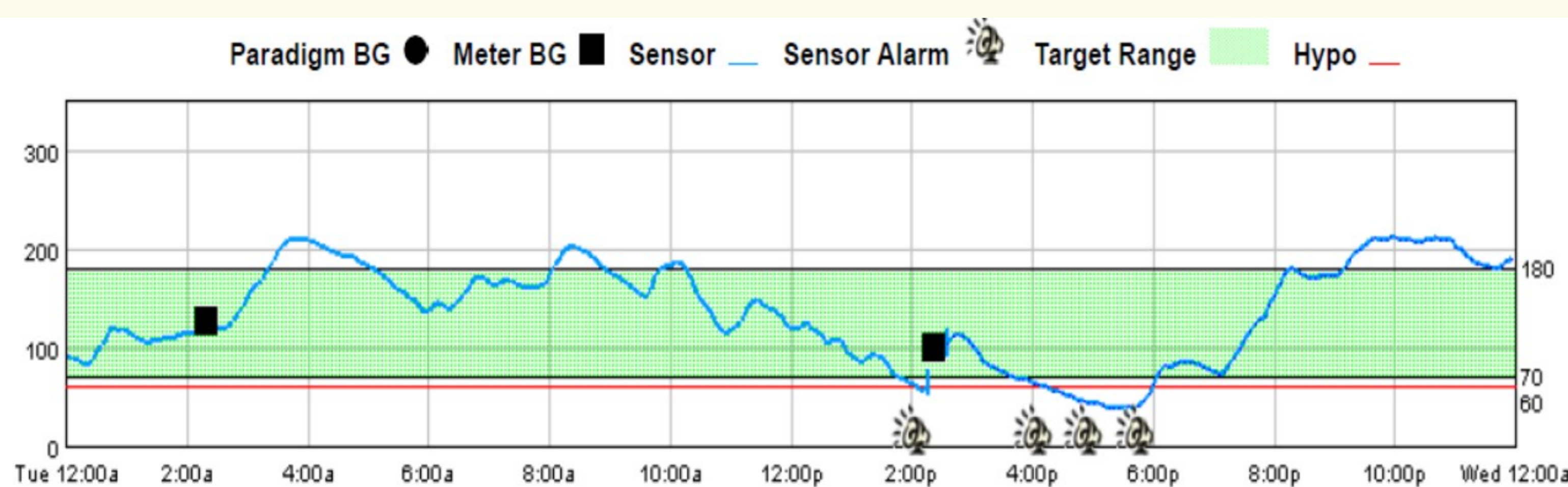


Figure(4): AUC for Hypoglycemia during day time of fasting (p<0.001 for all)

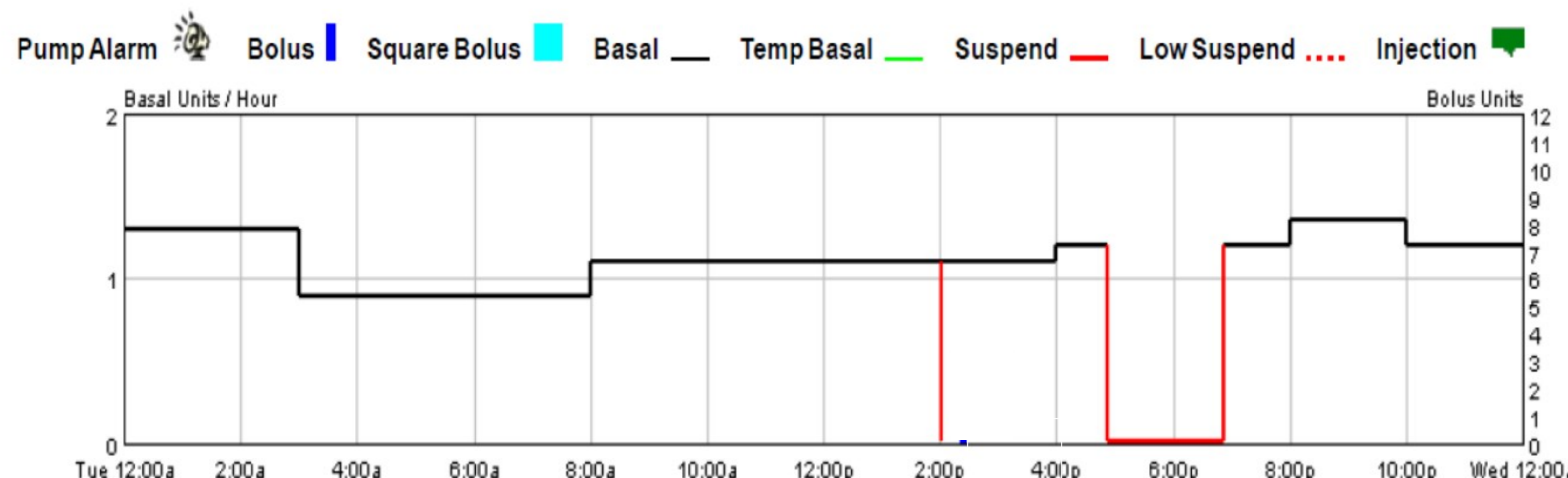
CONCLUSION

❖ This prospective observational study revealed that sensor-augmented insulin pump therapy with automated low-glucose insulin suspension has the potential to reduce exposure to major hypoglycemic events in patients with type 1 diabetes during Ramadan requiring breaking the fast.

❖ Fasting was feasible and patients maintained their glycemic control without compromising safety.



Insulin Delivery



Figure(1): Afternoon hypoglycemia during fasting suspended by LGS feature