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BASAL-BOLUS INSULIN THERAPY VS SLIDING SCALE INSULIN IN THE MANAGEMENT OF TYPE 2 DIABETES PATIENTS IN A CORONARY CARE UNIT

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ABSTRACT

Objective: To compare the efficacy and safety of a basal bolus insulin with that of sliding scale.

Study Design: Descriptive cross sectional study.

Place and Duration of Study: This study was conducted at AFIC-NIHD Rawalpindi from Oct to Dec 2014.

Methods: We conducted a quasi experimental study to compare the efficacy and safety of a basal-bolus insulin regimen with that of sliding-scale insulin (SSI) in patients with type 2 diabetes. A total of 89 patients received either a basal-bolus regimen comprising both regular and NPH insulin (*n*=46) or a standard SSI protocol (*n*=43). NPH insulin was given twice daily and regular insulin before meals. The starting dose of insulin for insulin-naïve patients who received the basal-bolus regimen was 0.3 units/kg/day in underweight patients, 0.4 units/kg/day in normal weight patients, 0.5 units/kg/day in overweight patients and 0.6 units/kg/day in obese patients. Patients who had been on insulin therapy previously received the same total daily dosage (TDD) of insulin that they were previously being treated with. In the SSI regime, regular insulin was given three times per day for blood glucose >140 mg/dl before meals.

Results: The mean admission blood glucose was 246 mg/dl in the basal-bolus group and 234 mg/dl in the SSI group. A mean blood glucose target of <180 mg/dl was achieved in 63% of patients in the basal-bolus group and in 26% of those in the SSI group. The difference in mean daily blood glucose between groups ranged from 34mg/dl to 61mg/dl with an overall difference of 37 mg/d (*p*=0.005). Despite increasing insulin doses, 33% of patients treated with SSI had mean blood glucose > 240 mg/dl. Hypoglycemia occurred in 13% of patients in the basal-bolus group and 5% of the SSI group.

Conclusion: Treatment with basal-bolus insulin resulted in significant improvement in glycemic control compared with that achieved with the use of SSI alone, although the incidence of hypoglycemia was greater. Our study indicates that a basal-bolus insulin regimen is preferred over SSI in the management of hospitalized patients with type 2 diabetes admitted to a coronary care unit.

Keywords: Hyperglycemia, Diabetes, Insulin, Sliding scale, Basal-bolus, Mean blood glucose.

INTRODUCTION

Two-thirds of people admitted to a coronary care unit (CCU) have impaired fasting glucose, impaired glucose tolerance, newly detected diabetes, or established diabetes[1,2]. Prospective studies have consistently reported that these dysglycemic patients have increased mortality and increased risk of in-hospital complications (including multi-organ failure and infection)[3]. Mortality is correlated to the degree of dysglycemia[3]. Furthermore, patients with acute myocardial infarction (AMI) whose glucose levels normalize after admission experience lower mortality than patients with persistent hyperglycemia[4].

The overwhelming majority of diabetic patients admitted to hospital are managed using sliding scale insulin (SSI) protocols, which have been shown to provide poor glycemic control and exhibit numerous deleterious effects[4]. Despite the evidence in support of intensive glycemic control in hospitalized patients, blood glucose control continues to be deficient and is frequently overlooked on medical and surgical wards[5]. Recent consensus guidelines developed by the American Association of Clinical Endocrinologists (AACE) and the American Diabetes Association (ADA)have recommended a goal range of 140-180 mg/dl in acute critical illness[6]. The guidelines emphasize the use of a basal-bolus insulin regimen to manage in-hospital hyperglycemia.

There are three components to a basal-bolus regimen: basal insulin, meal or nutritional bolus insulin, and correction insulin[6]. The ideal

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basal insulin provides a constant 24-hour peakless level of insulin to suppress the liver's release of glucose during the fasting state and between meals[7]. Glargine and Detemir are newer insulin analogs that provide relatively peakless basal insulin. Meal time bolus insulin is designed to prevent the predicted postprandial rise in glucose. Bolus insulin is best provided with one of the rapid-acting analogs (lispro, aspart, or glulisine) with each meal[7]. Correction insulin is intended to lower hyperglycemic glucose levels, but not to cover nutritional hyperglycemia. Rapid-acting analog formulations are the best choice as correctional insulin for patients who are able to eat. Before each meal, the mealtime bolus insulin dose and the correction insulin dose can be added and administered simultaneously[6].

A recent multicentred controlled trial[8] showed a basal/bolus regimen with a split-mixed regimen of intermediate Neutral Protamine Hagedorn (NPH) and regular insulin resulted in equivalent glycemic control compared to a regimen of detemir once daily and aspart before meals in patients with type 2 diabetes. In Pakistan, where healthcare resources are scarce, this combination of NPH and regular insulin represents a viable economic alternative to the long-acting plus short-acting analog basal-bolus regimen.

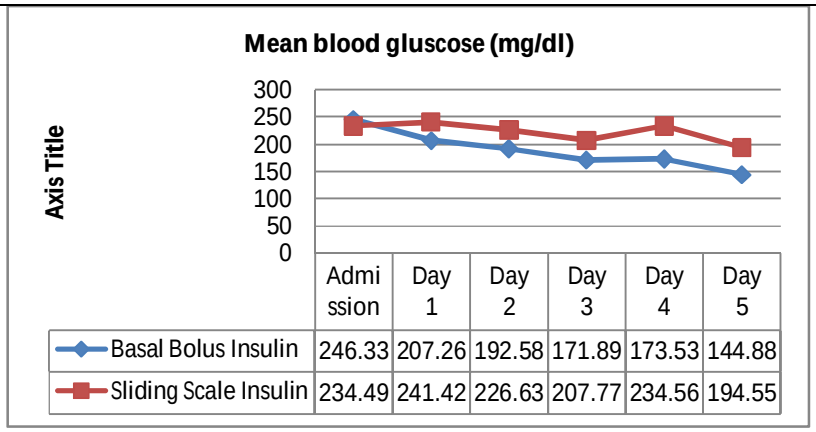

Figure-1: Line Graph comparing Mean Daily Blood Glucose levels (in mg/dL) between the Basal Bolus Insulin and Sliding Scale Insulin Groups.

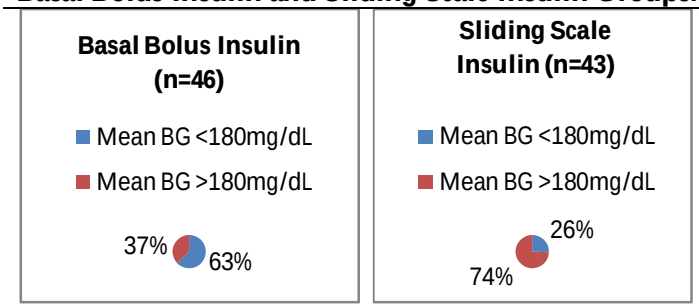

Figure-2: Pie charts comparing the efficacy of basal-bolus insulin with sliding scale insulin in maintaining a mean glucose of <180 mg/dL.

Table-1: Hospital SSI Protocol.

Blood Glucose Level (in mg/dL)	Dose of Regular Insulin (in units)
≤140	0
141-199	2
200-249	4
250-299	6
300-349	8
350+	10

MATERIAL AND METHODS

In this descriptive cross-sectional study, we enrolled 89 patients who were known to have a history of diabetes for over 3 months, aged 26 – 80years, and admitted to the coronary care unit with a blood glucose level between 140 and 400 mg/dl. Further inclusion criteria included diabetes treatment with either diet alone, insulin or any combination of oral anti-diabetic agents and the absence of diabetic ketoacidosis. Exclusion criteria included subjects without a known history of diabetes, use of corticosteroid therapy, subjects expected to undergo surgery during the hospitalization course, patients with

clinically relevant hepatic disease, serum creatinine 3.0 mg/dl, and pregnancy.

This study was conducted at the Armed Forces Institute of Cardiology (AFIC), Rawalpindi, Pakistan. All patients were managed by members of the cardiology department, who received a copy of the assigned treatment protocol. No follow-up visit after discharge was included in this study. Patients were randomly assigned to receive either SSI or a basal-bolus regimen. Oral anti-diabetic drugs were discontinued on admission.

46 patients were randomized to receive a basal-bolus regimen comprising both regular and NPH insulin (Fig-1) while 43 patients received a standard SSI protocol (Table-1). NPH insulin was given twice daily and regular insulin before meals. The starting dose of insulin for insulin-naïve patients who received the basal-bolus regimen was 0.3 units/kg/day in underweight patients, 0.4 units/kg/day in normal weight patients, 0.5 units/kg/day in overweight patients, and 0.6 units/kg/day in obese patients. Patients who had been on insulin therapy previously received the same total daily dosage (TDD) of insulin that they were previously being treated with. Patients on the basal-bolus regimen received correctional insulin prior to breakfast, lunch and dinner, in addition to their dose of NPH and regular insulin. Their TDD was recalculated every day, whereby their new TDD was the sum of the previous day's TDD and any correctional insulin they had required in the previous day. In the SSI regime regular insulin was given three times per day (before meals) for blood glucose >140 mg/dl as per the usual hospital protocol.

Table-2: Mean Daily Blood Glucose levels (in mg/dL) in the Basal Bolus Insulin and Sliding Scale Insulin Groups.

Basal Bolus Insulin Mean Blood Glucose ±1.96SEM	Sliding Scale Insulin Mean Blood Glucose ±1.96SEM	Significance value (Independent Samples t Test)
187.5 ±15.5	224.5 ±20.0	p=0.005

Table-3: Comparison of Mean Glucose Level (in mg/dL) during entire duration of CCU admission between Basal Bolus Insulin and Sliding Scale Insulin Groups.

	Basal Bolus Insulin Mean Blood Glucose ±1.96 SEM	Sliding Scale Insulin Mean Blood Glucose ±1.96 SEM
Admission	246.3 ±38.7	234.5 ±34.3
Day 1	207.3 ±25.4	241.4 ±27.5
Day 2	192.6 ±20.3	226.6 ±21.5
Day 3	171.9 ±18.3	207.8 ±25.8
Day 4	173.5 ±20.4	234.6 ±35.8
Day 5	144.9 ±21.9	194.5 ±38.8

The goal of insulin therapy was to maintain fasting and pre-meal blood glucose levels below 180 mg/dl while avoiding hypoglycemia. The primary end point was to determine differences in glycemic control between treatment groups as measured by the mean daily blood glucose concentration. Statistical analysis was performed using the SPSS software package. Change in blood glucose during the study period was analyzed by the independent samples t-test. A *p* value of 0.05 was considered significant.

RESULTS

Eighty nine patients with type 2 diabetes admitted to the coronary care unit were recruited. Forty six 46(51.6%) patients were randomized to receive basal-bolus insulin and 43(48.3%) to receive SSI. There were no significant differences in the mean age, racial distribution, weight or admission blood glucose between treatment groups. The most common admitting illnesses included acute coronary syndrome (42%), heart failure (20%), valvular heart disease (18%), and arrhythmias (9%). Overall, the patients in the basal-bolus insulin group received higher doses of insulin than patients in the SSI group.

Patients treated with basal-bolus insulin had better glycemic control than those treated with SSI. The mean admission blood glucose for all patients was 240.6 ± 25.9 mg/dl. The mean admission glucose values in the basal-bolus insulin and SSI treatment groups were 246.3 ± 38.7 mg/dl and 234.5 ± 34.3 mg/dl respectively (p=0.655). Mean blood glucose during the entire stay in CCU was 187.5 ± 15.5 mg/d in the basal-bolus group and 224.5 ± 20.0 mg/dl in the SSI group. The difference in mean daily blood glucose between groups ranged from 34 mg/d to 61 mg/dl with an overall difference of 37 mg/d. During the admission 29 patients (63%) of the basal-bolus group achieved the target mean blood glucose of <180 mg/dl while only 11 patients (26%) from the SSI group achieved this. Despite being on maximal doses of insulin, 14 patients (33%) from the SSI group had mean blood glucose levels >240 mg/d, compared to 4 patients (9%) from the basal-bolus insulin group. (Table-2,3)

Hypoglycemia (defined as blood glucose <70 mg/dl) occurred in 6 patients (13%) in the basal-bolus group, and in 2 patients (5%) from the SSI group. This was treated on the ward with either oral or intravenous dextrose, and no episode of hypoglycemia resulted in any adverse outcome. There were no glucose readings <40 mg/dl.

DISCUSSION

Our study showed that treating diabetic patients in CCU with a basal-bolus insulin regimen resulted in superior blood glucose management compared to a sliding scale insulin regimen alone. Despite persistent expert recommendations urging its abandonment, the use of sliding-scale insulin remains pervasive in hospitals[6]. Evidence for the effectiveness of sliding-scale insulin is lacking after more than 40 years of use[9]. A SSI regimen treats hyperglycemia after it has already occurred instead of preventing it from happening[10]. Other factors may explain the suboptimal glycemic control achieved in hospital. Treatment of other co-morbid conditions is often the priority for physicians during hospital admission. Fear of hypoglycemia, and a reluctance to treat raised blood glucose until it exceeds 200 mg/dl also contribute to raised patient glucose levels in hospital[10]. Finally, physicians frequently stop their patient's previous outpatient treatment and initiate sliding-scale coverage with regular insulin, a practice associated with limited therapeutic success and suboptimal glycemic control[10].

CONCLUSION

In summary, our basal-bolus insulin algorithm using NPH intermediate insulin and regular insulin before meals is a more effective regimen than SSI for glucose control in patients with type 2 diabetes in a coronary care unit. Despite the simplicity of SSI, this regimen does not provide adequate glycemic control and should not be used in the management of patients with diabetes in the CCU.

Conflict of Interest

This study has no conflict of interest to declare by any author.

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