Journal of Endocrinology and Diabetics Research

Research Article

A SCITECHNOL JOURNAL

Experience with Automated Insulin Dose Adjustment Based upon Computerized Formula in a Tertiary Care Diabetes Center

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Abstract

Background: With increasing burden of diabetes, existing system with limited trained medical personals especially in a developing country with poor health system will not be able to cope patient load. So an automated insulin dose adjustment based upon computerized algorithms might be a need of the hour.

Objective: To determine the efficacy and safety of automated insulin dose adjustment model based upon computerized formula in diabetic out-patient clinic at a tertiary care center

Material and Methods: This was case control study, conducted from (16 October 2020 to 15 May 2021) on 120 diabetic patients. Patients were attended thoroughly after addressing all ethical issues (described below) and prescription was given to them either generated by software or compiled by diabetes experienced fellow endocrinology. Then cases were followed after seven days for diabetes control.

Results: Our study was conducted on 120 cases, 60 in each group. There was no significant difference in our outcome parameters i.e. Mean fasting blood sugar, mean 2-hours post lunch blood sugar and mean 2-hours post dinner blood sugar and episodes of hypoglycemia between the two groups. In Group-S, 1.6% (n=1) cases developed episodes of hypoglycemia and in Group-F, 1.6% (n=1) cases developed episodes of hypoglycemia (p=1.00). Mean fasting blood sugar was 121.95 ± 16.22 mg/dl in Group-S and was 121.60 ± 16.46 mg/dl in Group-F (p=0.91). Mean 2-hours post lunch blood sugar was 182.45 ± 36.43 mg/dl in Group-S and was 181.45 ± 36.44 mg/dl in Group-F (p=0.88). Mean 2-hours post dinner blood sugar was 182.32 ± 29.66 mg/dl in Group-S and was 180.31 ± 28.66 mg/dl in Group-F (p=0.71).

Conclusion: So we concluded that use of automated insulin dose initiation and adjustment models based upon computerized algorithms are comparable to insulin dose initiation and adjustment by experienced physician. So our automated insulin dose initiation and adjustment model might help clinician at heavily burdened diabetic clinics. But we recommend it supervised use in such clinical settings.

Keywords: Heavily burdened diabetic clinics; Physician aiding software; Automated insulin dose initiation and adjustment model

Introduction

Prevalence of Diabetes is increasing in world especially in developing countries. Changing lifestyle in developing countries, urbanization and increased life expectancy are proposed causes of that increasing burden [1-5]. Based on the most recent International Diabetes Federation (IDF) report, the number of people with diabetes will increase from 425 million in 2017 to 629 million by 2045 [6].

Best management strategies to manage diabetes include healthy lifestyle and good dietary habits and proper pharmacological interventions [7-10]. Insulin therapy requires skilful adjustment of dosage in DM management [11]. Integrated model of diabetes care has shown promising results in terms of metabolic parameters [12]. With increasing burden of disease, existing system with limited trained medical personals especially in a developing country with poor health system will not be able to cope patient load. So an automated insulin dose adjustment based upon computerized algorithms might be a need of the hour. Software must be very accurate to suggest insulin dosage on entered blood glucose levels so that better outcomes with improved HbA1c and fewer hypo and hyperglycaemic episodes can be achieved in out-patient management [13].

Similar software systems are also introduced for insulin dose calculation of in-patients [14,15]. A real-time cellular-enabled Blood Glucose (BG) meter and Glytec's Glucommander™ Clinical Decision Support Software (CDSS) use in diabetic patients effectively lowered HbA1c, treated patients safely, and maintain those improvements over 12 months period [16]. In another study done on in-patients by Newsom R et al, Glycemic management improved with use of eGMS based on computerized insulin algorithm [16].

Diabetes Management Centre (DMC) of Services Hospital Lahore, Pakistan (SHL) has a physician aiding software, which has weight based formula for prescription and dose adjustment of insulin dosage. That formula is patient's weight based and adjust doses of insulin on values of Self-Monitoring of Blood Glucose (SMBG) entered in software. We hypothesized that the use of automated insulin dose adjustment models based upon computerized algorithms will improve glycaemic control and work flow at heavily burdened diabetic clinics.

Objective

To determine the efficacy and safety of automated insulin dose adjustment model based upon computerized formula in diabetic out-patient clinic at a tertiary care center

Operational Definitions

- Computer based insulin formula for prescription and dose adjustment of insulin, used in DMC Services hospital was assessed for its efficacy and safety. It is based on BMI and other signs of insulin resistance (hepatomegaly, acanthosis nigricans and waist circumference)
- High BMI: BMI ≥ 23 kg/m2 at first visit of study
- Hypoglycemia: Any blood sugar value less than 70 mg/dl in Self-Monitoring Of Blood Glucose (SMBG) was labeled as Hypoglycemia

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Received: August 8, 2021; **Accepted:** August 23, 2021;

Published: August 30, 2021

Materials and Methods

Study design: Prospective case control study.

Study settings: Diabetes management center, Services Hospital Lahore, Pakistan.

Duration of study: 6 months (16-10-2020 to 15-05-2021).

Sampling Technique: consecutive, non-probability.

Sample size: 120 (60 in each group).

Inclusion criteria

Age 18-70, both genders, Insulin initiation by software and if medical officer agrees with software prescription

Exclusion criteria

Pregnancy, CKD, CLD, IHD, Foot ulcer, Antibiotic prescription, complicated cases needs consultant endocrinologist review

Data collection procedure

After approval from IRB SHL and HOD endocrinology, cases that are initiated on insulin for the first time in DMC were recruited for study. A specialized proforma was developed to record the findings of this study. Informed consent was taken from each patient to participate in this study; they were briefed about objectives of this study, ensuring them confidentiality of the information provided and the fact that there is no risk involved to the patient while taking part in this study. Patients were attended by nursing counter for anthropometric measurements (height, weight, BMI) and Point of Care (POC) sugar. Then cases were attended by DMC Medical Officer (MO) to complete medical history and examination according to domains described in DMC software. Then prescription was generated by software and saved in system. Then MO assessed the prescription and if agreed with software plan and didn't think that prescription needs to be reviewed by Fellow or Consultant, he referred that case to fellow. Fellow was blinded to software made prescription and will do complete assessment of case and will made his own prescription for that case, that will also be saved in system. Next computer system was allowed to select the final take home prescription (with a label on that for future reference) for that case from the two prescriptions made for that particular case i.e. software made prescription (Group-S) and fellow made prescription (Group-F) in a randomized alternate computer based selection. Maximum number of new cases recruited for study per day was limited to 10 cases per Fellow to ensure complete clinical assessment of each case. At the first visit HbAIc was advised and recorded and each case was instructed to fully ensure the compliance to prescription, to keep SMBG for 7 days and then to consult in DMC again via telemedicine clinic. On next consultation, for both groups; SMBG record of last day was entered in software by attending doctor. As DMC software is a physician aiding software. We neither recommend nor trying to prove it as alternate to experienced physician. So the ethical concerns to recruit the cases for study; was addressed by strict exclusion criteria. According to best of our knowledge, we have fully tried to exclude all such cases that need mandatory input from fellow or consultant for prescription.

Data analysis

All parameters were entered in SPSS-24. Mean age and BMI at start of study will also be documented in each group. Frequency episodes of hypoglycaemia during whole treatment were noted in each group. Prescription of any other OHGs was noted. Fasting blood glucose, two hours post lunch blood glucose, two hours post dinner blood glucose (readings taken one day before consultation) for each case was documented. Comparison of all the parameters was done between two groups by using t test and p-value less than 0.05 was considered as significant. Data was stratified with regards to age groups, gender, BMI, Insulin regimen, Oral Hypoglycaemic Drugs (OHG) prescribed and baseline (HbA1c).

Table 1: Mean and SD of qualitative variables in study cases (n=120).

Quantitative variable	Group S (n=60) Mean	Standard Deviation	Group F (n=60) Mean	Standard Deviation	P-value
Age (years)	36.96	15.24	36.35	14.31	0.82
BMI at start of study (kg/m2)	24.5	4.26	24.7	4.11	0.79
HbA1c at start of study (%)	9.64	1.58	9.68	1.66	0.88
Follow-up FBS (mg/dl)	121.95	16.22	121.6	16.46	0.91
Follow-up post lunch blood sugar (mg/dl)	182.45	36.43	181.45	36.44	0.88
Follow-up post dinner blood sugar (mg/dl)	182.31	29.66	180.31	28.66	0.71

Results

Our study was conducted on 120 cases, 60 in each group. There was no significant difference in age, gender, BMI and baseline HbA1c between two groups. Similarly no significant difference was found in our outcome parameters i.e. Mean fasting blood sugar, mean 2-hours post lunch blood sugar and mean 2-hours post dinner blood sugar and episodes of hypoglycaemia between the two groups. In Group-S, 1.6% (n=1) cases developed episodes of hypoglycaemia & in Group-F, 1.6% (n=1) cases developed episodes of hypoglycaemia (p=1.00). Mean fasting blood sugar was 121.95 ± 16.22 mg/dl in Group-S and was 121.60 ± 16.46 mg/dl in Group-F (p=0.91). Mean 2-hours post lunch blood sugar was 182.45 ± 36.43 mg/dl in Group-S and was 181.45 ± 36.44 mg/dl in Group-F (p=0.88). Mean 2-hours post dinner blood sugar was 182.32 ± 29.66 mg/dl in Group-S and was 180.31 ± 28.66 mg/dl in Group-F (p=0.71).

Table 2: Frequency of episodes of hypoglycemia in study cases (n=120). There was no significant difference of risk of hypoglycemia between the two groups.

Episodes of hypoglycemia	Group S (n=60)		Group F (n=60)		p-value
	Frequency	Percentage	Frequency	Percentage	
Yes	1	1.6	1	1.6	1
No	59	98.4	59	98.4	
Total	60	100	60	100	

Stratification of mean fasting blood sugar, mean 2-hours post lunch blood sugar and mean 2-hours post dinner blood sugar was done with regards to age groups, gender, BMI, Insulin regimen, OHG prescribed

Table 3: Stratification of follow up blood sugar levels with regards to age and gender in study cases (n = 120). There was no difference between two groups after age and gender stratification except post lunch blood sugar found to be significantly better controlled in software group in females.

Confounder		Group S (n=60) Mean	Standard Deviation	Group F (n=60) Mean	Standard Deviation	P-value
Age < 35 years	Follow-up FBS (mg/dl)	118.32	15.65	118.37	14.97985	0.99
	Follow-up post lunch blood sugar (mg/dl)	196.72	19.17	190.96	26.1	0.33
	Follow-up post lunch blood sugar (mg/dl)	169.08	19.71	173.59	22.08	0.4
Age ≥ 35 years	Follow-up FBS (mg/dl)	124.54	16.35	124.24	17.36	0.94
	Follow-up post lunch blood sugar (mg/dl)	172.25	42.28	175.48	42.13	0.92
	Follow-up post lunch blood sugar (mg/dl)	188.34	31.49	185.81	32.39	0.77
Male	Follow-up FBS (mg/dl)	118.42	9.58	118.06	10.05	0.88
	Follow-up post lunch blood sugar (mg/dl)	175.6	36.88	175.6	36.88	1
	Follow-up post lunch blood sugar (mg/dl)	173.63	28.58	173.63	28.58	1
Female*	Follow-up FBS (mg/dl)	118.42	9.58	125.92	21.34	0.08
	Follow-up post lunch blood sugar (mg/dl)	175.61	36.88	190.81	34.72	0.11
	Follow-up post lunch blood sugar (mg/dl)	173.64	28.58	188.48	27.07	0.04

Table 4: Stratification of follow up blood sugar levels with regards to baseline BMI and HbA1c in study cases (n = 120)*.

Confounder		Group S (n=60) Mean	Standard Deviation	Group F (n=60) Mean	Standard Deviation	P-value
BMI < 23 kg/m2	Follow-up FBS (mg/dl)	129.75	13.93	128.64	14.44	0.76
	Follow-up post lunch blood sugar (mg/dl)	189.25	44.82	191.05	44.32	0.87
	Follow-up post lunch blood sugar (mg/dl)	173.6	26.61	172.23	25.52	0.84
BMI ≥ 23 kg/m2	Follow-up FBS (mg/dl)	118.05	16.03	118.81	16.53	0.86
	Follow-up post lunch blood sugar (mg/dl)	179.05	31.53	179.04	32.78	0.99
	Follow-up post lunch blood sugar (mg/dl)	183.67	29.37	183.51	29.47	0.98
HbA1c < 8.0%	Follow-up FBS (mg/dl)	113.45	7.312	112.36	8.36	0.59
	Follow-up post lunch blood sugar (mg/dl)	175.63	29.5	175.56	29.5	0.99
	Follow-up post lunch blood sugar (mg/dl)	190.63	28.8	190.73	29.8	0.99
HbA1c ≥ 8.0%	Follow-up FBS (mg/dl)	123.85	17.09	122.22	17.16	0.71
	Follow-up post lunch blood sugar (mg/dl)	183.45	37.91	183.01	36.92	0.96
	Follow-up post lunch blood sugar (mg/dl)	178	28.76	178.5	28.41	0.96

Table 5: Stratification of follow up blood sugar levels with regards to Oral hypoglycemic drugs and insulin regimen prescribed in study cases (n = 120)*

Confounder		Group S (n=60) Mean	Standard Deviation	Group F (n=60) Mean	Standard Deviation	P-value
Oral hypoglycemic drugs prescribed	Follow-up FBS (mg/dl)	117.82	15.16	115.51	12.03	0.52
	Follow-up post lunch blood sugar (mg/dl)	181.38	30.42	181.21	32.58	0.98
	Follow-up post lunch blood sugar (mg/dl)	181.82	28.16	180.59	27.66	0.87
Oral hypoglycemic drugs not prescribed	Follow-up FBS (mg/dl)	134.33	12.95	131.39	18.11	0.47
	Follow-up post lunch blood sugar (mg/dl)	185.66	51.68	184.43	42.62	0.92

	Follow-up post lunch blood sugar (mg/dl)	175.8	30.66	179.86	30.83	0.61
BD Insulin regimen prescribed	Follow-up FBS (mg/dl)	121.48	14.97	121.45	15.8	0.99
	Follow-up post lunch blood sugar (mg/dl)	205.03	29.7	192.15	33.35	0.12
	Follow-up post lunch blood sugar (mg/dl)	159.15	20.54	171.91	25.72	0.04
QID Insulin regimen prescribed	Follow-up FBS (mg/dl)	122.51	17.91	122.07	19.13	0.93
	Follow-up post lunch blood sugar (mg/dl)	154.85	22.12	150.57	27.36	0.51
	Follow-up post lunch blood sugar (mg/dl)	206.18	22.6	207.93	19.17	0.75

and baseline HbA1c. P-values are depicted in respective tables (Table 3 to Table 5).

Discussion

Automated insulin dose adjustment models based upon computerized algorithms are in limited use. On research of available literature, few studies are available on such models. Majority of such models were test for insulin dose calculation in hospital admitted patients. Like Ullal et al. studied Epic's Foundation system insulin calculator for dose calculation for a meal based on blood sugar levels and amount of carbohydrate. However this review summarized information about insulin dosing software and calculators used as computerized decision support systems or electronic Glucose Management Systems (eGMS) [16]. Our study was conducted in real time scenario on patients after addressing all ethical issues. In another study by Dinglas et al. dose of insulin in 22 patients was calculated by a standard insulin dosing chart and 11 patients were calculated by the gluco stabilizer software program. The gluco stabilizer software program was superior in achieving glucose values in target range at delivery (81.8% vs. 9.1%; P<.001) compared with standard insulin dosing without increasing maternal hypoglycemia (0% vs. 4.3%; P=.99). Patients whose insulin dosing was prescribed by the gluco stabilizer software program also had lower mean capillary blood glucose values compared with the standard insulin infusion (102.9 ± 5.9 mg/dL vs. 121.7 ± 5.9 mg/dL; P=0.02). This study was conducted on pregnant ladies with diabetes for calculation of insulin infusion dosage in hospital stay [17]. On the other hand, our study was a comparative study in out-patient settings, comparing insulin dosing by health care provider and software, it was conducted on 120 cases. In software group, 1.6% (n=1) cases developed episodes of hypoglycemia & in fellow group also, only 1.6% (n=1) cases developed episodes of hypoglycemia (p=1.00). Mean fasting blood sugar on follow up visit was 121.95 ± 16.23 mg/dl in software group and was 121.60 ± 16.46 mg/dl in doctor prescription group (p=0.91). Mean 2-hours post lunch blood sugar was 182.45 ± 36.43 mg/dl in software group and was 181.45 ± 36.44 mg/dl in doctor prescription group (p=0.88). Mean 2-hours post dinner blood sugar was 182.32 ± 29.66 mg/dl in software group and was 180.31 ± 28.66 mg/dl in doctor prescription group (p=0.71). A retrospective study by Aloi et al, evaluated 993 non-ICU patients treated with subcutaneous basal bolus insulin therapy managed by a provider compared to an electronic glycaemic management system. They evaluated averages blood glucose levels, hypoglycaemic episodes and number of cases who achieved target blood sugars (140 mg/dL-180 mg/dL). 47% and 62% cases were in target in health care provider insulin dose adjustment and managed by electronic glycaemic management system respectively. Percentage of hypoglycaemic events (<70 mg/dL) was 2.6% and 1.9% health care provider insulin dose adjustment and managed by electronic glycaemic management system respectively. Again that was a study at in-patient settings where dose was calculated before each meal. Although our study was at out-patient settings, but it too proved that software system equal to experienced health care provider in insulin prescription.

Conclusion

So we concluded that use of automated insulin dose initiation and adjustment models based upon computerized algorithms are comparable in terms of efficacy and safety to insulin dose initiation and adjustment by experienced physician. So our automated insulin dose initiation and adjustment model might help clinician at heavily burdened diabetic clinics. But we recommend it supervised use in such clinical settings.

Conflict of the Interest

There was no conflict of interest of any author involved in the study.

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