A PROSPECTIVE STUDY OF PRESCRIBING PATTERN OF INSULIN IN PATIENTS WITH TYPE 2 DIABETES MELLITUS ADMITTED IN MEDICINE WARDS

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ABSTRACT

Objectives: The prevalence of diabetes mellitus is increasing exponentially. The present research is mainly focused on studying the prescription pattern and rationality of insulin prescribed in patients with type 2 diabetes. It also reviews the acceptance of insulin therapy in type 2 diabetes patients. This research focuses on events of adverse drug reaction and also reviews adherence with the latest American Diabetes Association guidelines.

Methods: A study was conducted in 50 diabetic patients admitted in medicine wards. Patients were included in the study only after obtaining a written informed consent form. Fasting blood sugar and post-prandial blood sugar levels were noted on the day of admission and on the day of discharge.

Result: Out of 50 patients, human actrapid (HAI) according to sliding scale was the most commonly prescribed (66%) insulin, followed by HAI+lantus (30%) and mixtard (4%). In addition to insulin, 23 patients (46%) were given oral hypoglycemic agents, out of which the majority (60.8%) were on combination therapy with metformin, sulfonylureas, and dipeptidyl peptidase 4 inhibitors. A total of 28% of patients had shown adherence and acceptability with the therapy. About 86% of prescriptions in the present study were adhered to the guidelines of the American Diabetes Association.

Conclusion: The study shows that HAI therapy, according to the sliding scale, remains the first choice of treatment in type 2 diabetes patients in rural areas where data are insufficient. Poor adherence was observed among the patients toward insulin therapy, which may be due to a lack of awareness.

Keywords: Human actrapid, Oral hypoglycemic agents, Adherence, Type 2 diabetes mellitus, Sliding scale.

INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder, characterised by signs such as hyperglycemia, glycosuria, and sometimes increased ketone levels in the blood. Hyperglycemia is defined as a fasting blood glucose level ≥126 mg/dL and/or post-prandial blood sugar after 2 h (PP2BS) level ≥ 200 mg/dL. It is divided into 2 types. Type 1 is considered insulin-dependent DM/Juvenile onset DM [1].

The prevalence of DM is increasing exponentially every day. The prevalence of diabetes in India has risen from 7.1% to 8.9% during the period of 2009–2019. At present, 25.2 million adults are estimated to have impaired glucose tolerance. Out of 25.2 million adults, 12.1 million are >65 years of age. It is also estimated that nearly 57% of adults with diabetes are undiagnosed in India, which is approximately 43.9 million. In the 10th edition of Diabetes Atlas published by the international diabetes federation, it is said that by 2045, the global diabetes burden is expected to increase to 784 million and up to 115.4 million in India [2]. Diabetes is ranked among the 10 leading causes of mortality globally, with cardiovascular diseases, respiratory diseases, and cancer [3].

Insulin plays a major role in glucose metabolism in our body, and it is secreted from the beta cells of the islets of Langerhans of the pancreas. It was discovered in 1921 by Banting and Best. Insulin is a small protein in humans that contains 51 amino acids. Insulin has several preparations, which are mainly divided into two types: Short-acting and long-acting. Examples of short-acting insulin are regular insulin, human actrapid (HAI) insulin, lispro, etc. Isophan/neutral protamine hagedorn (NPH), insulin detemir, insulin glargine, insulin degludec, premix insulin, or mixtard (70% NPH and 30% regular) are the examples of intermediate to long-acting insulin preparations [4].

Insulin is commonly used in the treatment of type 1 DM (T1DM) patients with or without complications [5]. In India, a mixed trend of prescribing HAI (according to sliding scale) and insulin mixtard is seen commonly. With modern co-formulation, this trend is still continuing. Prescriptions with basal insulin are given in selected patients (alone or in combination with food) [6].

Not only pharmacological treatments, but some of the natural products are also been researched to be given for the management of diabetes/control glycemic index in patients, apart from anti diabetic drugs [7].

Hypoglycemia is considered the most common and most lethal side effect of insulin. It is characterised by palpitation, dizziness, and tremors, which are reverted by the administration of glucose orally or parenterally. It can also be confirmed biochemically by a plasma glucose value of <70 mg/dL with or without symptoms. Sometimes symptoms may not occur till the plasma glucose level reaches 55 mg/dL [8].

Acceptance and adherence to insulin treatment can be hindered by some common factors that are encountered by the patients [9]. These factors are fear of hypoglycemia, worsening of diabetes condition, guilt or feeling of failure of self-management, daily injection burden, etc. Correct execution of each attribute of the injection process is a key to achieving success in insulin treatment [10].

The purpose of the study is to observe the prescribing pattern and rationality of insulin usage in patients admitted in wards of the Department of Medicine at a tertiary care teaching hospital, Piparia, Vadodara, and adverse drug reaction, if any.

METHODS

Aim and objectives

Aim

To study the prescription pattern of insulin in patients with type 2 diabetes admitted in wards of the Department of Medicine at the Tertiary Care Teaching Rural Hospital.

Objectives

1. To study the prescribing pattern of Insulin in patients with type 2 diabetes admitted to wards of medicine department in a tertiary care teaching hospital
2. To study the acceptance and adherence of patients to insulin treatment
3. To study the dose, frequency of administration, and change in insulin therapy, if any
4. To report and analyse the adverse drug reaction.
5. To analyse adherence with the American Diabetes Association (ADA) guidelines.

Study design

1. Type of study: A prospective type of observational study
2. Place of study: Dhiraj Hospital, a tertiary care teaching hospital attached to S.B.K.S. Medical Institute and Research Centre, Piparia, Vadodara
3. Source of data: Patient records from the ward of medicine department
4. Sample description: Samples are collected by simple randomization
5. Duration of study: 6 months (July 2023–January 2024).
   Ethics committee (approval no.: 23/48, date: July 7, 2023)

It is a prospective non-interventional and observational type of short study which is carried out in the wards of the medicine department of Dhiraj hospital, which is a rural tertiary care teaching hospital affiliated with SBKS Medical Institute and Research Centre, running under Sumandeep Vidyapeeth. The study was initiated after approval by the Institutional Ethics Committee of Sumandeep Vidyapeeth.

Participants were included in the study after obtaining a written informed consent form, in their vernacular language, after a thorough explanation about the purpose and method of the study, and through a patient information sheet, before enrolling the patient for this study. Data were taken at the time of admission and at the time of discharge of the patients. Relevant data were gathered from their case files. Information about the patient was recorded in a case record form.

6. Selection criteria
a. Inclusion criteria
   - Patients who were admitted in the wards of medicine department with Type 2 DM (T2DM)
   - Patients who were treated with insulin therapy
   - Patients of either sex of age 18 and above
   - Patients who were having T2DM with a comorbid condition.

b. Exclusion criteria
   - Patients were not willing to participate and did not give consent to the study
   - Patients with T1DM
   - Women with gestational diabetes and breastfeeding
   - Patients aged <18 years.

Material/equipment for study

Case record form of patient admitted in wards of the Department of Medicine, Dhiraj General Hospital.

A suitable data collection form was prepared and used to collect the required data. The demographic details, prescription pattern, and blood sugar level were recorded in a case record form.

Various medications, including insulin used to treat high blood sugar, along with their doses, routes, frequency, and duration of treatment, were recorded. Relevant laboratory investigations were also recorded.

Confidentiality of patient information was properly ensured using code numbers in place of the patient's personal identification.

Sample size

This is a prospective observational study.

In the initial phase of the study, we calculated the sample size with the prevalence of 26.03% (According to reference no. [11]) and applied the given formula:-

SAMPLE SIZE (n)=4×p (positive factor) q (negative factor)/L^2 (margin of error)

p=0.26 q=0.74 (1-p) L=0.1 (taking 10% margin of error)

n=4×0.26×0.74/(0.1)^2

n=76.96

The duration of our study was 6 months. Hence, according to the patient flow in our hospital and applying our inclusion criteria, we were able to achieve the sample size of 50 patients.

Statistical methods

In this study, the sample size was taken as 50.

A suitable data collection form was prepared and used to collect the required data.

Data were collected by case record form and were entered in Microsoft Excel, and its percentage analysis was done. The Chi-square test and paired T-test were calculated with the help of GraphPad.

RESULTS

Demographics and patient disposition

A total of 50 patients with T2DM were taken in the study, and their prescription pattern of insulin is been observed. In this study, there were 29 males and 21 females. . As details showed in Table 1, the majority of the patients were from the age group of 51–60 years, with a mean age of 56.7±7.84. The majority of the patients (46%) have their HBA1C level between 10 and 10.9, with the mean value of 10.95±0.98. A total of 35 out of 50 patients were admitted with the diagnosis of uncontrolled DM. From all the patients who were given the insulin therapy, HAI is the most prescribed (66%) one, followed by HAI+lantus (glargine) (30%). Mixtard (70% isophan insulin: 30% regular insulin) is the least prescribed insulin registered from this study. Nearly half of the patients (46%) were given oral hypoglycemic agents with insulin therapy, in which 11 patients were given a fixed dose combination (FDC). The majority of the patients were on metformin, sulfonylureas, and dipeptidyl peptidase 4 (DPP-4) inhibitors. There were 33 patients with comorbid conditions.

Safety and tolerability

A total of eight adverse events were seen in 8 (16%) patients during the study. All events were of hypoglycemia, and the events were mild in severity, and they all were resolved. Apart from a reduction in insulin dose and glucose uptake, there is no other treatment for adverse drug reactions. The average requirement of insulin during the treatment period of the patients was 21–30 units daily in 16 (32%) patients, followed by 41–50 units/day in 13 (26%) patients. Mean insulin usage for the patients per day was 27.4 units with or without oral hypoglycemic agents. As details showed in Table 2, out of 50 patients, 14 patients had shown adherence and acceptability with the therapy. The rest of the patients showed low adherence with anti-diabetic management, and also the patients prefer oral hypoglycemic agents more than insulin subtypes. No patients of T2DM were taking insulin therapy at home, as they all were at oral hypoglycemic agents.

Effectiveness

Treatment with insulin, especially with HAI, a combination of HAI+lantus and mixtard, has shown significant effects in lowering the blood glucose level of the patients. Fig. 1 shows a comparison of fasting blood sugar (FBS) levels before and after management with insulin, with or without oral hypoglycemic agents (OHA). For post-prandial blood sugar (PPBS) level, 18 patients (36%) had blood sugar levels in the range of 201–250 mg/dL, and 251–300 mg/dL, and some patients (6%) had blood sugar levels more than 351 mg/dL. After therapy, the majority of the patients (42%) had their blood sugar level in the range of 201–251 mg/dL. The number of patients in the range of 251–300 mg/dL had significantly reduced to 10%, and no patient had a blood sugar level more than 351 mg/dL. Table 3 showed post treatment blood sugar level.

Table 4 shows a significant change in the blood sugar level after management with insulin in every age group of people. The blood glucose level is significantly reduced after management with insulin. Normal FBS level is achieved in 34 patients.

DISCUSSION

After evaluation of 50 patients with T2DM who were on insulin therapy, number of males were on higher side than females and the same trend was seen in other studies [12-14], Sedentary lifestyle plays important role in the prevalence of the T2DM as 72% of the patient of the study were from age group of 41–60 years. A similar trend was seen in previously published studies [6,15]. The majority of Type 2 diabetes patients require insulin therapy due to damage of the beta cells of Langerhans. The combination of oral hypoglycemic agents with insulin is required for the patient with T2DM to achieve glycemic control and delay the deterioration of beta-cells. Combination therapy for T2DM patients is helpful for patients who are on oral hypoglycemic agents and find it difficult to have glycemic control with the aid of diet and exercise [16]. Insulin can also be indicated in patients with T2DM if the hemoglobin A1c level continuously remains above 10.0% or uncontrolled diabetes due to ineffective oral hypoglycemic agents [17].

Consistent hyperglycemia causes microvascular and macrovascular complications such as diabetic retinopathy, diabetic nephropathy, diabetic foot, atherosclerosis, hypercoagulability, cardiovascular disease, coronary heart disease, abdominal obesity, and hyperlipidemia [18]. In our study, it was also observed that patients having poor glycemic control were suffering from similar complications and morbidities.

In this study, the major reasons for initiating insulin therapy in T2DM patients were majorly uncontrolled hyperglycemia and ineffective oral hypoglycemic drug therapy, which is similarly seen in Baruah *et al.* [19]. Other reasons include infection, chronic diseases like heart failure, and chronic kidney disease.

As shown in Fig. 2, short-acting insulin analog HAI is the most commonly prescribed insulin according to the sliding scale and given in 33 patients out of 50. This is different from the study done by Kovil *et al.* [20], as premix insulin was used commonly, but a similar trend of prescribing short-acting insulin was seen in the study done by Tiwari *et al.* [6] and Acharya *et al.* [21]. Some other studies noted that long-acting insulin glargine gives a better effect on controlling glycemic indices, such as FBS level and HbA1C, of the patients [22].

Table 5 showed that among 23 patients who were on OHAs with insulin therapy, the majority of the patients (60.8%) were on combination therapy of metformin+sulfonylureas or metformin+DPP-4 inhibitors. Similar trends have been observed by Singla *et al.*, where DPP-4 inhibitors and sulfonylureas are selected with metformin or as the second-line drug therapy [13]. A cross-sectional study by Agarwal *et al.* and Patel *et al.* [23,24] had also shown a similar prescribing pattern of these drugs, and Gunda *et al.* [25] had also shown triple drug therapy
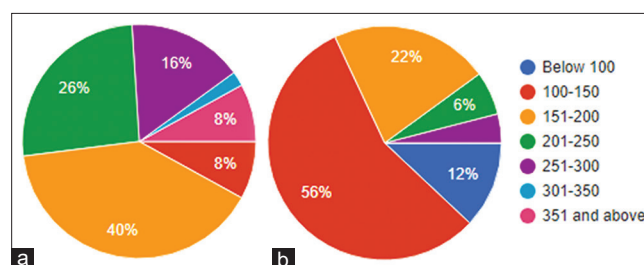
Fig. 1: Fasting blood sugar level comparison before and after insulin management. (a) Before treatment, (b) After treatment

Table 1: Demographic study (n=50)

Parameters	Number of patients (n=50) (%)
Age group	
41–50 years	14 (28)
51–60 years	22 (44)
61–70 years	12 (24)
>71 years	2 (4)
	(Mean age 56.7±7.84)
HBA1c level	
8–8.9	2 (4)
9–9.9	2 (4)
10–10.9	23 (46)
11–11.9	14 (28)
12–12.9	9 (18)
	(Mean HBA1c level 10.95±0.98)
Comorbidities with type 2 diabetes mellitus	
Hypertension	15 (30)
Renal disease	7 (14)
Heart disease	4 (8)
Diabetic neuropathy	4 (8)
Diabetic foot	2 (4)
Trigeminal neuralgia	1 (2)
Average duration of stay	(Mean 3.46±0.97)

HBA1c: Hemoglobin A1c

Table 2: Adherence/no adherence with the treatment (n=50)

Adherence and acceptability with treatment	14
No adherence: (Reasons)	36
Forgetfulness	17
Fear of side effects	12
Lack of desire/motivation	7

Table 3: Categorization of blood sugar level post-management (at the time of discharge) in patients (n=50)

Blood glucose level post treatment (at the time of discharge) with insulin (n=50)			
Fasting blood sugar (FBS)	Controlled (Normal) (<140 mg/dL)	Partially Controlled (Prediabetes) (141–199 mg/dL)	Not satisfactory (Diabetes) (>200 mg/dL)
	34	11	5
PPBS (Post-prandial blood sugar)	Controlled (Normal) (<140 mg/dL)	Partially Controlled (Prediabetes) (141–199 mg/dL)	Not satisfactory (Diabetes) (>200 mg/dL)
	8	34	8
p-value	<0.001		

for uncontrolled T2DM. Table 4 shows the variety of OHAs used with insulin in our study.

After management with insulin and with/without oral hypoglycemic agents, control of FBS was significantly better, but it did not give the same results for PPBS. For control of PPBS, HAI was given according to
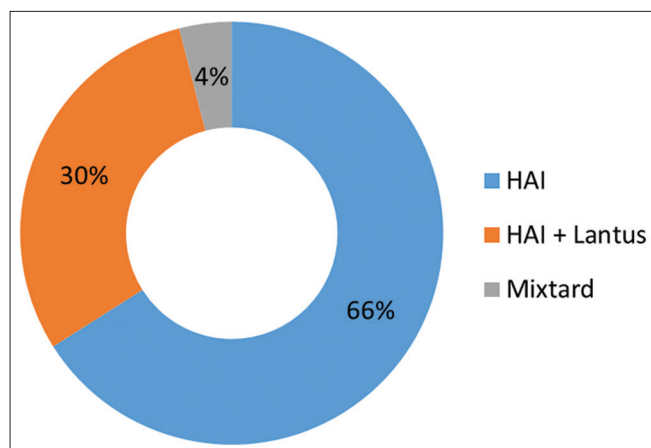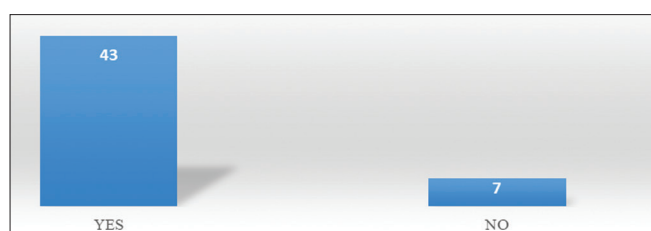
Fig. 2: Prescription pattern of insulin

Fig. 3: Adherence with American Diabetes Association guidelines in 50 patients (n=50)

Table 4: Mean fasting blood sugar comparison before and after insulin management (at the time of discharge) (n=50)

Age group	Mean FBS before treatment	Mean FBS after treatment	p-value
41–50	173.57±20.14	124.35±24.40	<0.001
51–60	227.36±19.97	161±17.70	<0.001
61–70	287.83±20.08	241.66±24.29	<0.001
>71	356±5.65	252±25.45	<0.0061

FBS: Fasting blood sugar

Table 5: Use of oral hypoglycemic agents with insulin in 50 patients (n=50)

Insulin usage without OHA	27 (54%)
Insulin usage with 1 OHA	8 (16%)
Metformin	4
Linagliptin	2
Repaglinide	2
Insulin usage with 2 OHA	14 (28%)
Glimepride+metformin	8
Vildagliptin+metformin	2
Teneligliptin+metformin	2
Remogliflozin+vildagliptin	2
Insulin usage with 3 OHA	1 (2%)
Glimepride+metformin+voglibose	

OHA: Oral hypoglycemic agents

a sliding scale to partially control the blood sugar level in the present study. However, some literature supported the use of HAI over regular human insulin due to their fast onset and short duration of action [26]. Sliding scale insulin therapy is most commonly prescribed with Actrapid and gives great results in the FBS range >140 mg/dL–<180 mg/dL. In patients with blood sugar level >180 mg/dL and with chronic kidney disease, there is add on with basal insulin is seen with the use of sliding scale regular insulin to manage the hyperglycemia [27]. This trend is also shown in the present study. DPP-4 inhibitors and sodium glucose co-transport 2 inhibitors also play a significant role in reducing PPBS levels [28], which are also used in the present study.

Out of 50 prescriptions of T2DM patients with insulin, there were a total of 23 prescriptions with oral hypoglycemic agents, and from that, 11 (47.8%) were with FDC. The use of FDC is somewhat lower in the present study compared to others [29]. The majority of the patients (54%) were on insulin monotherapy, which was similar to the study of Ardoino *et al.* [30].

In 50 prescriptions, there were a total of 104 drugs prescribed, which were for DM. Out of 104 drugs, 65 (62%) drugs were insulin, and 39 (38%) drugs were oral hypoglycemic agents. According to this study, about 2.08 anti-diabetic drugs were prescribed per patient to control hyperglycemia, which was not avoidable due to a high HbA1c level. A similar trend is seen in a previous study, which shows an increased number of drugs prescribed in diabetic patients, and the incidence of polypharmacy was higher [31].

According to ADA guidelines, insulin therapy would be considered if the HbA1c level >9. Furthermore, it includes the use of metformin and sulfonylureas as the main line treatment. According to it (Fig. 3), 86% of treatments in the present study were adherent to guidelines, which is similar to Tiwari *et al.* [6] and higher than other studies [32].

CONCLUSION

The present study shows the usage of insulin in type 2 diabetes patients in rural areas, where the data are insufficient for the treatment trend. This study reveals that the prescription pattern of insulin follows nearly the same trend of using HAI according to a sliding scale in India. It also shows the combination of HAI with a long-acting insulin combination for controlling hyperglycemia. Oral hypoglycemic agents used with insulin were giving positive outcome for the treatment due to great adherence with the present guidelines. There were low adverse events, in which hypoglycemia is still the common one. The results of the present study provide real-life data, which will help formulate newer strategies to improve patient care with type 2 diabetic patients.

AUTHOR CONTRIBUTION

All the listed authors have contributed to each and every aspect of the research article, including analysis, data collection, generation of the results, etc.

CONFLICTS OF INTEREST

None.

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None.

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