RESEARCH PAPER

Influence of Adverse Events on Glycemic Control and Factors Associated with Poor Outcomes Among Patients with Diabetes on Insulin Therapy

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Received: 25th May, 2026; **Revised:** 6th June, 2026; **Accepted:** 8th June, 2026; **Available Online:** 17th June, 2026

ABSTRACT

Aims

To evaluate the effect of adverse events on glycemic control and determine the risk factors associated with poor glycemic control and the development of adverse events secondary to insulin use.

Methods

Two hundred and fifty-six patients with type 1 and type 2 diabetes mellitus on insulin therapy were included in a cross-sectional study upon presenting as in-patients, over a period of 12 months. Patient data and most recent HbA1c values were obtained. Poor glycemic control was defined as HbA1c ≥ 9%. Descriptive and analytical statistics such as independent t-test and regression analyses were applied to the data to generate results.

Results

The mean HbA1c value of the study population was 9.5 ± 1.9% (80 mmol/mol). The difference in the mean HbA1c values between the participants who experienced adverse events secondary to insulin use and those who did not experience the same was 9.6% vs. 9.0% (81 mmol/mol vs 75 mmol/mol, p=0.016). In the regression analyses, none of the study parameters were found to be significant risk factors for poor outcomes.

Conclusion

Adverse events secondary to insulin use significantly impact glycemic control. However, no significant risk factors for poor glycemic control and the development of adverse events were identified.

Keywords: Adverse event, Diabetes mellitus, Glycemic control, HbA1c, Insulin therapy, Risk factor.

How to cite this article: Padmanabha PH, Awayz A, Varghese JO, Sekhar NC, Kumar TR, Bai JS, Khan PA, Kumar MM. Influence of Adverse Events on Glycemic Control and Factors Associated with Poor Outcomes Among Patients with Diabetes on Insulin Therapy. Int J Drug Deliv Technol. 2026;16(61s): 519-525. DOI: 10.25258/ijddt.16.61s.57

Source of support: Nil.

Conflict of interest: None.

INTRODUCTION

The revolutionization in the management of diabetes began with the discovery and evolution of insulin and is still progressing with the search for novel insulin delivery systems; presently the injectable form is most widely used. Although diabetes has been around for several thousand years, its prevalence has shown a gradual but persistent increase over the last century, especially marked in the latter half. The WHO factsheet reported in 2018 that the number of individuals with diabetes has risen from 108 million in 1980 to 422 million in 2014 globally. In India, the International Diabetes Federation has reported a prevalence of 8.9%, with the number of affected individuals standing at over 77 million [1].

With the increase in the prevalence of diabetes and the progression of the disease, more individuals are being shifted to insulin for the better management of diabetes and prevention of its complications. It is estimated that 150–200 million individuals are using insulin worldwide. Albeit insulin is deemed as the most effective glucose-lowering medication for diabetes [2], it has been observed in routine clinical practice that patients on insulin for several years and even those involved in clinical trials have failed to achieve the optimal glycemic targets. Multiple and complex factors are assumed to be responsible for this failure [3, 4]. Insulin is considered a drug with a narrow therapeutic index and is categorized by the Institute for Safe Medication Practices as a high-risk medication [2]. The use of insulin, being an injectable drug, has a greater tendency to be influenced by misconceptions and technical difficulties in comparison to oral hypoglycemic agents (OHAs) [5].

As with other medications, the use of insulin is associated with some undesirable effects. Certain adverse effects of insulin such as hypoglycemia, weight gain, mitogenic properties, and increased risk of cardiovascular events are related to its pharmacology [6]. Whereas, several adverse effects of insulin such as lipodystrophy, pain, and local reactions are a consequence of inadequate knowledge regarding handling and administration techniques [7]. These adverse effects, although not life-threatening and often inconsequential to physicians, may become cause a patient to discontinue insulin therapy leading to poor glycemic control, and will serve as a barrier in the overall management of diabetes [8].

Glycemic control is measured in the form of glycated hemoglobin (HbA1c), which indicates the average blood glucose levels over the preceding three months [9]. The recommended target HbA1c levels as per recent guidelines issued by the American Diabetes Association and International Diabetes Federation lies in the range of 6.5–7% (48–53 mmol/mol), whereas most national bodies accept a value of up to 7.5% (58 mmol/mol) [4]. The impact of every 1% reduction in glycated hemoglobin has been demonstrated by the data from UKPDS (UK Prospective Diabetes Study) to reduce the incidences of diabetes-related death by 21%, myocardial infarction by 14%, microvascular complications by 37%, and peripheral vascular disease by 43%[4]. Indubitably, all evidence indicates that there are adverse influences on health and outcomes of diabetes as a result of extremely poor glycemic control (HbA1c > 10% [86 mmol/mol]) [10].

With the importance of glycemic control being highlighted, it comes to light that a majority of patients with diabetes are unable to meet their glycemic targets despite being on insulin therapy. A survey conducted in the USA in 2002 revealed that merely 26.7% of the participants achieved the HbA1c target of < 7% (53 mmol/mol) [4]. This percentage is likely to be lower in a developing country such as India, with ethnically diverse and deprived populations [10]. Our study evaluated the influence of insulin-induced adverse events on glycemic control and determined the predictors of adverse events and poor glycemic control.

METHODS

1. *Subjects, Materials, and Methods:*

1.1 *Study Design and Site:* A cross-sectional study of patients with diabetes on insulin therapy was designed. Patients were sampled by convenience sampling method, upon admission as in-patients under the Department of Endocrinology, Ramaiah Hospitals, Bangalore, India.

1.2 *Study Participants:* Type 1 and type 2 diabetes mellitus patients of all age groups who were using insulin with the most recent HbA1c values (not older than 3 months) were included in the study upon admission as in-patients under the Department of Endocrinology between August 2019 to July 2020. The patient's informed consent for participation in the study was taken, and confidentiality was strictly maintained. The patients who were unwilling to give consent and those who used insulin devices other than syringes and insulin pens were excluded from the study. A total of 256 patients were recruited. The primary outcome to be evaluated was glycemic control, measured by HbA1c values.

1.3 *Data Collection:* Patient data were collected using pre-designed structured questionnaires and face-to-face patient interviews.

1.4 *Operational definition:* Glycemic control was stratified based on HbA1c values [11]; as shown in Table 1. The occurrence of adverse events secondary to insulin use was recorded based on whether the patient had experienced any of the listed effects in the past 2 weeks, along with objective evidence, if available. Local reactions and lipodystrophy were documented upon inspection.

1.5 *Statistical Analysis:* Statistical analysis was performed using Statistical Package for Social Sciences (SPSS, version 20, IBM). Descriptive statistics such as mean, SD, frequency, and percentages were used to represent demographic variables, insulin-use details, and prevalence of adverse events post-insulin administration in the study population. Data are represented in the form of frequency distribution tables. Analytical

statistics such as multinomial and binary logistic regression were applied to determine risk factors for poor glycemic control and development of adverse events; an independent t-test was used to measure the mean difference in HbA1c values between groups, in addition, the Chi-square test was used to find associations between variables. A p-value < 0.05 was considered statistically significant.

1.6 Ethical Consideration: The study protocol was approved by Ramaiah Medical College, the Human Ethics Committee, and the Institutional Scientific Committee and all recommendations were acknowledged. Informed consent of every participant was taken after explaining the aims and objectives of the study. Strict confidentiality of all the data obtained during the study was maintained.

Table 1: Stratification of glycemic control based on HbA1c values.

HbA1c value (%)	HbA1c value (mmol/mol)	Glycaemic Control
< 6	< 42	Excellent
6-6.4	42-46	Good
6.5-7.5	48-58	Fair
7.6-8.9	60-74	Unsatisfactory
≥ 9	≥ 75	Poor

RESULTS:

1.7 Participants' demographics, diabetes history, and insulin-use characteristics:

This study included a total of 256 participants, all of whom were on insulin for the management of their diabetes. The majority (63.3%) were men, and the mean age was found to be 59.5 ± 12.9 years, with ages ranging from 10 to 92 years. A large proportion (39.8%) of the study participants were illiterate, while about a quarter of them (25.4%) had attained higher education. Upon enquiring, 23.4% of the participants claimed to have irregular dietary habits.

When assessing diabetes and insulin-use characteristics, close to half of the study population had a history of diabetes between 5–15 years (47.3%) duration, with 44.9% of them being maintained solely on insulin. A total of 46.1% of the participants had been using insulin for a duration of 1–5 years, and the insulin syringe was the most widely used device (153n). The majority of participants (57.8%) were prescribed insulin injections twice a day. Results from the questionnaire on insulin-use practices revealed that 99.2% of individuals in the study re-used needles, with 41.8% of them reusing up to 10 times. A large proportion, constituting 90.6% of participants admitted to routinely practicing injection site rotation.

1.8 Glycemic control, prevalence of Adverse Events, and HbA1c difference between groups:

The mean HbA1c value of the 256 study participants was found to be 9.5 ± 1.9 % (80 mmol/mol), with the highest observed value being 16.0% (151 mmol/mol). Stratification of the patients based on glycemic control, determined by HbA1c values, revealed that a larger proportion of patients demonstrated unsatisfactory (28.1%) and poor (57.8%) glycemic control, as shown in Table 2.

Table 2: HbA1c values and glycemic control observed in the study population.

HbA1c range (%)	HbA1c range (mmol/mol)	Glycaemic Control	Percentage (%)
< 6	< 42	Excellent	1.6
6-6.4	42-46	Good	2.7
6.5-7.5	48-58	Fair	9.8
7.6-8.9	60-74	Unsatisfactory	28.1
≥ 9	≥ 75	Poor	57.8

In interviews with patients about insulin-induced adverse events, 71.7% reported experiencing at least one in the past 2 weeks. Of these, the adverse events having the highest prevalence were hypoglycemia (46.9%), pain (42.2%), and lipodystrophy (18.0%).

An independent t-test was performed to verify the HbA1c value among subjects who experienced adverse events and those that did not experience adverse events secondary to insulin use, which demonstrated that there exists a significant mean difference in HbA1c values between the two groups (p = 0.016), as represented in Table 3.

Table 3: Representation of results of independent t-test for difference in mean HbA1c values between participants who experienced Adverse Events and those who did not experience Adverse Events.

Group	N	Mean HbA1c (%)	Std. Deviation	Mean diff./p-value
Adverse Event Not Experienced	74	9.019	1.8358	-.6465 p-value=0.016 *

Adverse Event Experienced	182	9.665	1.9664	

*Note: statistical significance at $p < 0.05$ at 95% CI.

1.9 Logistic regression analyses of factors associated with poor outcomes:

Binary logistic regression analysis was performed to determine the risk factors for the development of insulin-induced adverse events. Factors such as sex, duration of diabetes and insulin use, treatment modalities, number of injections per day, and insulin delivery device used were independently analyzed, none of which were found to be significantly associated with the development of adverse events. Similarly, these factors along with some additional parameters were assessed as predictors of poor glycemic control, returning no significant value ($p > 0.05$). Table 4 and Table 5 represent the results of the regression analyses.

Table 4: Logistic regression analysis of factors associated with the development of insulin-induced adverse events among patients with diabetes.

Study Parameters	**Sig. (p-value)**	**Odds Ratio (OR)**	**95% C. I. for OR**	
			Lower	**Upper**
Sex				
Male	0.604	0.832	0.415	1.668
Female	> 0.05	1.00 (ref)	---	---
Treatment modalities	0.946	1.019	0.592	1.754
Insulin alone	> 0.05	1.00	---	---
Insulin + OHAs*				
Number of injections per day	0.811	0.800	0.129	4.960
1	0.831	0.833	0.156	4.451
2	0.673	1.486	0.236	9.355
3	0.588	1.650	0.269	10.109
4	0.435	1.00 (ref)	---	---
> 4				
Duration of diabetes	0.869	1.031	0.716	1.484
Duration of insulin use	0.358	1.264	0.767	2.084
Insulin device used	0.051	0.129	0.017	1.008
Syringe	0.141	0.210	0.026	1.682
Pen	0.055	1.00 (ref)	---	---
Both				

Note: statistical significance at $p < 0.05$ at 95% CI.

Table 5: Multinomial logistic regression analysis of factors associated with poor glycemic control among patients with diabetes on insulin.

HbA1c Interpretation	**Parameter Estimates**	**Sig.**	**OR**	**95% Confidence Interval for OR**	
				Lower Bound	**Upper Bound**
Good control (HbA1c ≤ 7.5)	Treatment modalities	.275	1.579	.696	3.586
	No. of injections per day	.837	1.071	.558	2.055
	Duration of diabetes	.679	.900	.546	1.482
	Duration of insulin use	.550	.811	.408	1.613
	Insulin device used	.067	1.761	.961	3.227
	Dietary habits	.678	1.223	.472	3.167
	Hypoglycaemia	.576	1.254	.567	2.774
	Reuse of needle	.455	1.858	.366	9.418
	Rotation of injection sites	.305	1.405	.734	2.688
	Lipodystrophy	.267	.511	.156	1.672
	Pain	.068	.462	.201	1.060
Unsatisfactory control (HbA1c 7.6-8.9)	Treatment modalities	.683	1.139	.611	2.121
	No. of injections per day	.518	1.181	.714	1.953
	Duration of diabetes	.268	.804	.547	1.183
	Duration of insulin use	.451	1.204	.743	1.950
	Insulin device used	.589	1.142	.707	1.844
	Dietary habits	.480	1.289	.637	2.608
	Hypoglycaemia	.729	1.113	.607	2.040
	Reuse of needle	.708	1.272	.361	4.480

	Rotation of injection sites	.715	1.107	.642	1.909
	Lipodystrophy	.259	.632	.284	1.403
	Pain	.864	.949	.521	1.727

Compared with category- Poor control (HbA1c ≥ 9%).
Note: statistical significance at $p < 0.05$ at 95% CI.

2. DISCUSSION:

Diabetes is a chronic and progressive condition and requires routine monitoring to determine the disease status of an individual, which is useful to guide physicians regarding the direction of treatment. HbA1c values are considered to be the most reliable measure of glycemic control and are therefore recommended by the American Diabetes Association to be performed at least twice a year for patients with controlled blood glucose levels and every 3 months for individuals with uncontrolled blood glucose readings [12].

The existing data suggest that glycemic control in the clinical setting is suboptimal despite being on insulin therapy, with the average HbA1c levels being in the order of 8-9% (64–75 mmol/mol) [4,13]. Several studies have analyzed this lack of achievement of glycemic control in terms of physician-related barriers and patient perspectives, with little consideration towards the influence of adverse drug reactions (ADRs) or adverse events associated with drug use. This study focused on gauging the impact of insulin-induced adverse events on the glycemic control of those individuals who experienced them, while further exploring the factors that are predictive of unfavorable outcomes such as the development of adverse events with insulin therapy and the presence of poor glycemic control.

The mean HbA1c of the participants in our study was found to be comparable with the range of values observed in several studies across nations [4, 13]. A median HbA1c of 8.5% (69 mmol/mol), with over 50% of participants falling in the range of 7.7–9.3% (61–78 mmol/mol) was reported by an audit conducted in Belgium in 2001, consisting of over 460 patients with Type I diabetes [14], whereas a study undertaken in Kuwait revealed that HbA1c values ≥ 8% (≥ 64 mmol/mol) were seen in 66.7% of the study population [15]. In our study, 57.8% of participants had poor glycemic control with HbA1c values ≥ 9% (≥ 75 mmol/mol). A reasonable explanation for this could be that the study population were in-patients admitted for the management of uncontrolled diabetes and its complications.

The most common adverse events reported by patients were hypoglycemia (46.9%), pain at the injection site (42.2%), and lipohypertrophy (18.0%), with 71.7% of subjects claiming to have experienced at least one of these adverse events in the past 2 weeks. It has been recorded that an average of 43 symptomatic episodes of hypoglycemia are experienced annually in patients with Type 1 diabetes mellitus, with the count for type 2 diabetes mellitus patients being 16 episodes per year, secondary to insulin use [16]. According to a study, clinically significant lipohypertrophy has a prevalence of approximately 20–30% and 4% in patients with type 1 and type 2 diabetes mellitus on insulin therapy, respectively [17].

In our study, individuals who experienced adverse events secondary to insulin use had higher HbA1c values in comparison to their counterparts who did not experience these events. This association has been demonstrated for individual ADRs by various studies. Case reports by Chowdhury *et al*. in 2003 and Wally Ahmed *et al*. in 2004 described 3 cases in which insulin-induced lipohypertrophy was the cause of poor glycemic control, identification, and management which resulted in significant improvements in HbA1c values [18,19]. In other cases, adverse events may indirectly result in poor glycemic control by having an unfavorable impact on medication adherence and contributing to the intentional omission of insulin, thus leading to poor glycemic control [20]. Among others, injection pain was found to be a significant independent risk factor for insulin omission in a study by Peyrot *et al*., in 2010 [21]; additionally, it has been noted by Perlmuter *et al.,* that patients who have experienced hypoglycemia in the past tend to develop certain behaviors such as reducing or skipping insulin dose as well as over-eating to prevent hypoglycemia as a result of anxiety and fear [22], further contributing to the loss of glycemic control.

Binary regression analysis performed to identify the independent risk factors for the development of adverse events yielded no significant results. This may be a consequence of taking into account patient reports of adverse events that occurred in the past 2 weeks and are not confirmed by any objective evidence. In general, ADRs are more likely to occur in individuals belonging to extremes of age, on multiple medications, having a previous history of ADR, and higher doses of the drug [23]. Similarly, multinomial regression analysis carried out to assess predictors of poor glycemic control did not produce any significant results. This does not resonate with the outcomes of the study by Khattab *et al.* that demonstrated multiple factors associated with poor glycemic control such as longer duration of diabetes, non-adherence to dietician

recommendations, and insulin management along with oral agents [13].

As the results of the regression analyses performed in our study are inconsistent with those reported in similar studies, the lack of significant results may be justified by collinearity between the parameters analyzed as well as the patient inclusion criteria. All the participants of the study were on insulin for the management of diabetes, indicating a pre-existing lack of control of diabetes and disease progression. Additionally, the subjects were in-patients who were admitted as a consequence of uncontrolled blood sugar levels or management of complications of diabetes such as diabetic foot, urinary tract infection, retinopathy, nephropathy, and neuropathy. In such cases, it is presumable that HbA1c values would be indicative of poor glycemic control as a result of disease status and progression rather than factors solely related to insulin use and adverse effects.

3. CONCLUSION:

A significant impact of adverse events on glycemic control was demonstrated in our study, with differences in the HbA1c values between the two groups of participants. However, no significant risk factors for poor glycemic control and the development of adverse events were identified. Further studies having superior study designs that assess causality are required to evaluate these factors predictive of poor outcomes in the management of diabetes.

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