Effect of Insulin Storage and Administration Methods on Long Term Glycaemic Control among Adult Diabetic Patients in a Kenyan Referral Hospital

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Insulin storage methods and the techniques of its administration impact on blood sugar control. A hospital based cross-sectional study was conducted to assess the effects of insulin administration techniques and storage on the long term control of blood glucose among 73 freely consenting adult diabetic outpatients at Kenyatta National Hospital. Participants were selected through convenient sampling and interviewed using a pre-designed questionnaire. Long term glycaemia control was assessed by measuring the blood levels of glycated haemoglobin. Ethical approval was granted by the institutional review board and participants' confidentiality was maintained throughout the study. Data analysis was done using STATA version 10 software; with statistical significance set at 95% confidence limit. Logistic regression was used to determine associations between glycated haemoglobin levels versus insulin storage methods and the administration techniques. Correct performance of the critical injection techniques (p=0.0001), insulin storage by refrigeration (p=0.041) and during travel (p=0.019) were associated with good long term glycaemic control. Patients need to be regularly encouraged on good insulin injection techniques and storage methods in order to improve long term glycaemic control.

Key words: Insulin storage, injection technique, glycated haemoglobin, glycaemic control

INTRODUCTION

Diabetes mellitus (DM), a chronic disease of metabolic abnormalities manifested as chronic hyperglycemia, has a prevalence of 4.4% globally and 4.5% in Kenya [1] that is expected to double by 2025 due to lifestyle changes and increased rural to urban migration. Monitoring of glycaemic control in diabetic patients is done through blood glucose testing or measurement of glycated haemoglobin (HbA1c). HbA1c testing is a surrogate marker of long term glycaemic control or how well the DM therapy and care plan has been working over the last 2–3 months [2, 3]. Results from the Diabetes Control and Complications Trial (DCCT) indicated that DM patients with HbA1c levels <7% can prevent DM-related complications [4], thus guiding the target HbA1c level for DM management. HbA1c levels are defined to be normal, borderline, and high if below 5.7%, between 5.7–6.9%, and 7% or more, respectively, with high HbA1c indicating poor overall glycaemic control [3].

Although two-fifths of DM patients in Kenya are on insulin therapy [1], they often fail to achieve optimal glycaemic control [5, 6]. A number of factors including lack of adherence, poor quality of insulin,

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inadequate insulin doses, inappropriate storage of insulin and incorrect insulin administration technique, may lead to high HbA1c amongst DM patients. There is paucity of local data on the relationship between the knowledge on insulin administration technique and its storage methods versus the long term glycaemic control among diabetic patients. The objective of this study was therefore, to find out the insulin storage methods and the injection techniques among adult diabetic outpatients in Kenyatta National Hospital (KNH) and relate them to their HbA1c levels.

METHODOLOGY

Study approval (reference number KNH-ERC/A/242) was granted by the Kenyatta National Hospital–University of Nairobi Ethics and Research Committee (KNH/UON-ERC). A cross sectional study was conducted at Pharmacy 15, KNH, between June and July 2015. Pharmacy 15 serves outpatients attending various medical clinics including the diabetes and endocrinology clinic. The sample size was calculated using the Fischer's formula [7] and a minimum sample size of 66 participants was determined. As such, a 10% was added to cater for the data losses and therefore, the participants recruited for the study were 73 freely consenting adult diabetic outpatients, 18 years and older, on insulin therapy refilling their monthly prescriptions at the Pharmacy. The participants, selected by convenient sampling, had to have been on insulin therapy for at least three months prior to the study. Critically ill patients and those with other co-morbidities were excluded from the study. A structured questionnaire was used for data abstraction. Coding ensured participant's confidentiality throughout the study.

The participants were assessed for insulin administration technique and insulin storage methods that they employed. Participants' socio-demographic characteristics were documented. Participants were then required to demonstrate their insulin injection techniques, which were evaluated against the internationally set standards of the American Diabetes Association (ADA) [2]. The participants' demonstration was termed correct if all the critical steps were performed correctly and incorrect if any of the critical steps was missed or performed incorrectly. The participant was also interviewed on how they stored and transported their insulin. Participants' HbA1c levels done in the recent 2-3 months period were captured. For the participants who had not had their HbA1c analyzed during the past 2-3 months, blood samples were collected and sent to the clinical chemistry laboratory, University of Nairobi, for determination.

The collected data was analyzed using the STATA statistical software version 10. Associations between the insulin storage methods and HbA1c as well as injection techniques and overall blood sugar control were computed using Chi square tests. The level of significance was set at 95% confidence limit and p-values ≤ 0.05 were termed statistically significant.

RESULTS

Socio-demographic characteristics of the study population

There was female preponderance of the study population at 63.0%. The mean age of the study participants was 53.6(±11.0) years, with the highest number of the participants (78.0%) being between 36-65 years. Patients aged less than 35 years were the minority at 5.5%. Over 90% of participants reported to

have had formal education and lived in urban areas. Slightly over ninety-five percent were not consuming alcohol (Table 1).

Table 1: Sociodemographic characteristics of study participants (N=73)

Characteristic	Frequency (%)
Age category (years)	
0-35	4 (5.5)
36-65	57 (78.1)
Above 65	12 (16.4)
Marital status	
Married	65 (89.0)
Single	8 (11.0)
Gender	
Male	27 (37.0)
Female	46 (63.0)
Occupation	
Employed	47 (64.4)
Unemployed	14 (19.2)
Retired	11 (15.1)
Student	1 (1.4)
Highest education level	
No formal education	4 (5.5)
Primary	17 (23.3)
Secondary	20 (27.4)
Tertiary	32 (43.8)
Residence	
Urban	65 (89.0)
Rural	8 (11.0)
Alcohol consumption status	
Former	24 (32.9)
Current	3 (4.1)
Never taken	46 (63.0)

Insulin injection technique

Overall, only 53.4% of the study participants correctly performed all the steps of insulin injection technique, as described by the ADA (Figure 1). Most participants (94.5%) performed step 5 (fixing the syringe to the needle) and step 8 (loading insulin into the syringe at room temperature) correctly. Loading the syringe with air equal to amounts of insulin units required, step 6, was the worst performed step with 47.9 % of the participants failing to do this crucial step. Approximately 60% of the patients performed step 3 (checking for clarity and detecting any precipitation, frosting and crystallization) and step 7 (injecting air into the vial at oblique to avoid vacuum) correctly. All other steps were performed correctly by over 60% of the participants (Figure 1).

Insulin storage and handling techniques

Table 2 presents data related to the storage and handling of insulin. Majority of the study participants (69.9 %) stored insulin, at home, in a tin with cotton wool dipped in spirit; while 30.1% used refrigeration. During travel, 91.8% of the patients stored insulin in a tin with cotton wool dipped in spirit, while 6.8% and 1.4% stored it in their bags and in wallets, respectively. Only 1.4% of the patients labeled a newly opened vial and none of the patients discarded the insulin vial after 28 days of use.

Table 2: Storage and handling of insulin

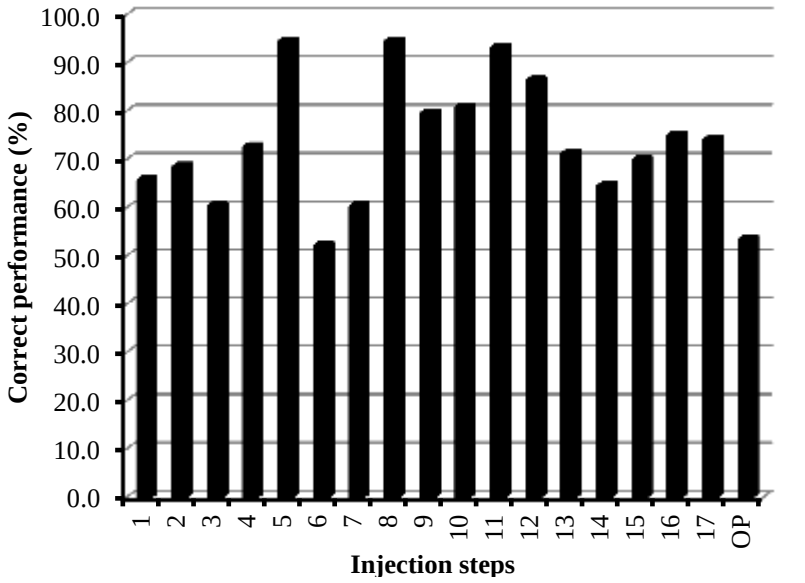
Variable	n (%)
Home storage	
Refrigeration	22 (30.1)
Cotton dipped in tin	51 (69.9)
Handling while travelling	
Bag	5 (6.9)
Container (tin/thermos)	67 (91.7)
Wallet	1 (1.4)
Labeling a newly opened vial	
Yes	1 (1.4)
No	72 (98.6)
Period before discarding	
After 28 days	0 (0.0)
Until empty	73 (100.0)

Values of glycated haemoglobin

Over half of the patients (53.4%) had supratherapeutic levels of HbA1c (> 7%) at the time of the study. The mean HbA1c was 8.1% (±3.6), displaying a high dispersion reflected in the obtained standard deviation. After exploring for factors which may be associated with long term blood sugar control (Table 3), it was found that insulin injection technique ($p<0.0001$), storage by refrigeration ($p=0.041$) and handling/ storage of insulin cotton wool dipped in spirit ($p=0.019$) were statistically significantly associated with optimal blood sugar control. Other factors such as demographics and overall performance in storage methods were not statistically significantly associated with adequate glucose control ($p>0.05$).

Table 3: Bivariate analysis on the factors associated with glycated haemoglobin

Variable	Glycated haemoglobin levels				p-value
	High (>5.7%)		Normal (<5.7%)		
Gender	**n**	**%**	**n**	**%**	
Male	14	0.2	12	0.2	1.000
Female	24	0.3	23	0.3	
Age (years)					
<35	0	0.0	4	0.1	0.077
35-65	30	0.4	27	0.4	
>65	8	0.1	4	0.1	
Marital status					
Married	32	0.4	6	0.1	0.264
Single	33	0.5	2	0.0	
Highest education level					
Informal	4	0.1	0	0.0	0.272
Primary	8	0.1	9	0.1	
Secondary	11	0.2	9	0.1	
Tertiary	15	0.2	17	0.2	
Random blood sugar					
High	31	0.3	11	0.2	<0.0001
Normal	7	0.1	22	0.3	
Low	0	0.0	2	0.0	
Overall performance in injection technique					
Correct	4	0.1	34	0.5	<0.0001
Incorrect	34	0.5	1	0.0	
Refrigeration					
Yes	16	0.2	6	0.1	0.041
No	23	0.3	28	0.4	
Storage					
Handbag	0	0.0	5	6.8	0.019
Container/ thermos-flask	38	52.0	29	39.8	
Wallet	1	1.4	0	0.0	



Key

1	Reading insulin vial
2	Check for the date of expiry
3	Check for clarity
4	Gentle rolling of insulin vial on the palm without agitation
5	Fixing the syringe to the needle
6	Loading syringe with air equal to the units
7	Injecting air into the vial at oblique angle
8	Loading insulin at room temperature
9	Loading insulin into the syringe in upright position
10	Flick top of the syringe needle
11	Using cotton wool and spirit to sterilize
12	Wait for spirit to fully vaporize before injecting
13	Pinching skin, injecting at 45 degrees
14	Inject insulin units
15	Press on injection site for 5 sec
16	Alternation of sites at every jab
17	Injection before or after meals.
OP	Overall Performance

Figure 1: Participants' performance of insulin injection steps as defined by the ADA.

DISCUSSION

The steps for correct insulin injection technique, as outlined by the ADA, are pertinent for ensuring optimal insulin quality, administration and bioavailability. Steps 1-3 (reading the label on insulin vial, checking expiry date and checking insulin clarity) avoid mix-ups and ascertain that the insulin is suitable for use. Failure to verify the pharmaceutical characteristics of insulin before use may lead to use of defective insulin displaying precipitation, frosting or crystallization. Steps 5-10 denote the correct

procedure for loading insulin into the syringes, paying emphasis to gently rolling of the insulin vial for even mixing and loading of air equal to units required into the vial. The air loaded into the vial allows smooth loading of insulin into the syringe and avoids creation of a vacuum in the container. Step 6 (loading the insulin vial with equal amounts of air) was performed incorrectly by most participants, indicating poor understanding of the importance of this step. Steps 11 and 12 involve skin preparation prior to injection, while steps 13-15 describe the actual injection process. The pinching of skin and injecting at about 45° (step 13) is critical for ensuring insulin is injected subcutaneously and not intramuscularly which may affect the absorption of insulin from injection site. The alternation of injection sites (Step 16) prevents development of lipodystrophy associated with overuse of a single site. Lipodystrophy would lead to erratic insulin absorption and hence unpredictable blood sugar levels. Step 17 deals with the timing of the insulin injection in relation to meals, in order to avoid post prandial hyperglycemia.

The various steps of insulin administration outlined chronologically ensure appropriate insulin delivery and absorption hence optimizing blood sugar control. It would be ideal for all patients to perform all steps correctly. The positive correlation between insulin administration technique and HbA1c levels in this study highlights the importance of training patients on correct injection technique and regularly assessing them for the performance. Previous studies on insulin administration technique have revealed that patients, and in some cases health care personnel, may not correctly administer insulin [8, 9].

The high percentage of participants in our study who did not have access to refrigerators closely relates to findings of previous local surveys [1, 10] which showed majority of diabetic patients did not have access to refrigeration. The use of containers with cotton wool dipped in spirit, that evaporates to keep cool temperatures, was widely used as a stop-gap measure for insulin storage in this study (both at home and while travelling). However, the effectiveness of this method is unclear as it is yet to be critically assessed and appraised [11]. Furthermore, the amount of cotton wool and spirit used, the frequency of replacing spirit and the size of the container are not standardized, hence some variability of the cooling effect is expected. Suboptimal insulin storage, hence questionable potency, was another likely cause for failure to achieve optimal glycaemic control amongst diabetic patients in our study. As insulin potency varies, so does its effectiveness and efficacy in patients, even after injection techniques have been successfully followed and applied.

Patented water activated cooling wallets, for instance, Frio® wallets [12], which consist of crystals with gel on contact with water, and that keep wallet contents cool by slow water evaporation, were not used by any of the participants in our study. The water activated cooling wallets serve as a good storage option for insulin while travelling and also at home in absence of refrigeration. All the insulin refills by the participants were done before lapse of the recommended 28 days in use period, during their monthly clinic appointments. Hence, the significance of discarding insulin after 28 days was unnoticed. Nevertheless, this knowledge should be imparted on all patients.

CONCLUSION

There were positive associations between long term glycaemic control and correct injection technique, refrigeration and storage of insulin on travel in cotton wool dipped in spirit in this referral hospital. As such, patients need to be regularly trained and assessed on their insulin administration technique. In addition, patients should be encouraged on good insulin storage and handling methods by all the healthcare givers involved in their chain of care.

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