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Impact of patient satisfaction with insulin pens on glycemic control

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ABSTRACT

Aim: Adherence to the insulin regimen is poor. The use of an insulin pen contributes positively to glycemic control by increasing patient satisfaction and adherence. The aim of this study is to analyze the influence of patients' opinions of insulin pen use on glycemic control in type 2 diabetes mellitus (T2DM).

Material and Method: 126 patients with T2DM who use insulin and inject it with insulin pens were included in the study. Patients' evaluations about the pens (ergonomics, ease of reading the dosage scale, dose selection, needle change, and ease of use of the insulin pen in general) were assessed. Glycemic parameters, demographic characteristics, and treatment protocol were recorded.

Results: Patients who perceived the use of the insulin pen as ergonomically 'excellent' had a significantly lower HbA1c (8.0±1.4%) (p=0.04). HbA1c was significantly lower in patients who perceived needle tip replacement as 'very easy' (8.0±1.6%) (p=0.04). No statistically significant relationship was found between the ease of reading the dosage scale and the HbA1c value (p=0.53). The HbA1c value decreased significantly in patients who rated the dosage selection as 'very easy' (8.1±1.7%) (p=0.02). The HbA1c value increased significantly in patients who rated the pen as 'difficult' to use (12.2±1.6%) (p=0.01).

Conclusion: In our study, we found that patients' opinions of insulin pen use may influence glycemic control parameters. HbA1c was better in patients who found the insulin pen as easy to use and good in ergonomics. In T2DM, patient assessment of insulin pen injection is related to glycemic control. New studies are needed to say whether this situation is related to the appropriate dose of insulin injection or adherence to therapy.

Keywords: Diabetes mellitus, insulin, injection, HbA1c

INTRODUCTION

The incidence of diabetes mellitus (DM) is increasing in our country (13.7%) as in the whole world (1). The American Diabetes Association (ADA) recommends a glycemic target of glycated hemoglobin (HbA1c) < 7% (53 mmol/mol) for the treatment of type 2 DM (T2DM) (2). Despite new pharmacological agents, many patients do not reach glycemic target values (3). A major obstacle to effective treatment of DM is lack of adherence (4). People with type 1 DM take insulin only. Some people with T2DM fail to control their blood glucose with diet, exercise, and oral hypoglycemic agents and require insulin. However, adherence to the insulin regimen is poor (5,6). There are numerous factors that influence patients' adherence to therapy. These include age, duration of disease, adverse events such as hypoglycemia or weight gain, injection method, pain on injection, number of daily injections,

and patient confidence in treatment (7). Improving the adherence to insulin treatment helps to reduce HbA1c levels and improve metabolic control (8). In addition, studies show that the injection method (such as the technology used, the prevention of lipohypertrophy by changing the injection site each time) can affect glycemic control by providing the appropriate dose and absorption of insulin, apart from patient compliance (9). Insulin therapy is administered with a syringe, insulin pen, or insulin pump. In patients with T2DM, insulin is usually injected with insulin pens. Instead of the syringe, the use of insulin pens contributes positively to glycemic control by increasing patient satisfaction and adherence (10). Over the years, different insulin pens have been developed to improve accuracy and ease of use. In order to increase the ease of use, many features of insulin pens

have been tried to be developed. These include portability, ease of reading the dose scale, ease of dose adjustment, ergonomic design, sturdiness, safety, and the ability to distinguish between pens in patients using multiple pens (different colors or thickness etc (11). Nowadays, there are various insulin pens with different characteristics and innovations among the conventional (with replaceable cartridge) and disposable (with single cartridge) insulin pens. Studies have shown that using the insulin pen that the patient prefers and is satisfied with will increase the success of the treatment (12) The aim of this study is to analyze the influence of patients' opinions of insulin pen use on glycemic control in T2DM.

MATERIAL AND METHOD

This cross-sectional study included patients with T2DM who were treated between September 2013 and March 2014 in Endocrinology Department of Kırıkkale University Faculty of Medicine Hospital. The study was approved by the Clinical Researches Ethics Committee of the Kırıkkale University (Date: 17.07.2013, Decision No: 14/01). All procedures were performed in accordance with the ethical rules and the principles of the Declaration of Helsinki.

Patients aged 18 to 70 years who had been using an insulin pen regularly for at least one month, used an insulin needle tip of the same brand and size, were motor and intellectually capable of self-administering an insulin pen, had no severe retinopathy affecting vision and had no severe neuropathies or motor deficits were enrolled in the study. Exclusion criteria were that patients were under 18 years of age and older than 70 years of age, used the insulin pen for less than 1 month, had severe retinopathy affecting vision, had severe neuropathy or motor deficits that could interfere with the use of the insulin pen, were unable to self-inject the insulin pen and were assisted by their relatives, and used needle tips of different brands and sizes. During this period, patients with a T2DM diagnosis using an insulin pen were evaluated consecutively, and patients who met the inclusion and exclusion criteria were included in the study. Care was taken to ensure that half of the patients enrolled in the study used disposable pens (with a prefilled insulin cartridge) and the other half used conventional insulin pens (with a replaceable insulin cartridge). During this 6-month period, a total of 126 patients were enrolled in the study. Patients had provided written informed consent. All patients underwent a physical examination and biochemical evaluation. Patients were asked questions about their demographic characteristics, disease characteristics, insulin treatment details, and ratings of the insulin pen they used. The presence of diabetic neuropathy was determined by the signs and

symptoms of peripheral neuropathy, including numbness in the hands and/or feet, dysesthesia and/or paresthesia, hypersensitivity to touch, burning pain, neuropathic foot ulcers, and decrease or loss of deep tendon reflexes. Patients' renal functions were evaluated by measurements of serum creatinine, microalbuminuria, and creatinine clearance. After exclusion of hematuria and urinary tract infections, values of albumin/creatinine ratio greater than 30 mg/g in the spot urine collected at least twice were accepted as diabetic nephropathy. Diabetic retinopathy was diagnosed by an ophthalmologist after an ophthalmologic examination. A 10-cm visual analogue scale (VAS) was used to assess pain during injection, starting with horizontal "No pain" and ending with "Unbearable pain" (13). Fasting blood glucose (FBG) and glycated haemoglobin (HbA1c) levels were recorded. For HbA1c analysis, cation exchange high performance liquid chromatography (HPLC) was used and for FBG and other biochemical tests, spectrophotometric method on Beckman coulter AU5800 (Beckman coulter Inc. CA, USA) autoanalyzer was used.

Patients' ratings of insulin pens in terms of ergonomics, ease of needle tip replacement, readability of the dosage scale, dose selection, and ease of use of the pen were assessed. Patients were asked their opinion on ergonomics with one of 5 different levels from very poor to excellent (very poor, poor, moderate, good, excellent). And they were asked their opinions on the ease of insulin pen use and the other three features with one of 5 different grades, from very difficult to very easy (very difficult, difficult, moderate, easy, very easy). The HbA1c values based on these 5 assessment groups were compared.

The SPSS 16 (Statistical Package for Social Sciences) program was used for statistical analysis of the results of the study. Results were expressed as mean±standard deviation (mean±SD). Descriptive statistics were performed for all variables. One-way ANOVA was used to determine if there were statistically significant differences between groups. Tukey's post-hoc test was used to determine where the difference existed between the groups. Shapiro-Wilk test was used to determine whether the distribution of the data was normal or not. Before correlation analysis, patient satisfaction status was graded. It was graded as very poor or very difficult, 1; poor or difficult, 2; moderately, 3; good or easy, 4; excellent or very easy, 5, and correlation analysis was performed between numeric parameters, not categorical. Pearson's correlation coefficient is preferred when the data are normally distributed, and Spearman Rank's correlation coefficient is preferred when the data are not normally distributed. The significance was evaluated at the $p < 0.05$ level.

RESULTS

One hundred twenty-six patients with a mean age of 55.3±11.1 years were included. 89 of the subjects (71%) were female. The mean duration of diabetes was 11.8±7.3 years and the mean duration of insulin use was 4.7±4.8 years. **Table 1** shows the demographic characteristics, microvascular complications, insulin pen types and laboratory findings of the subjects. Twenty-three (18.2%) patients had previously used other insulin pens. The remainder were either using an insulin pen for the first time or had previously used the same type of insulin pen. All patients used the same brand and size of needle tip (32 G - 6 mm). Only 53.2% of the patients used the needle tip once as recommended, while the others used it at least twice. The mean number of uses of the same needle tip was 1.76±1.1, and the mean intensity of needle pain was 2.8± 2.2. The number of needle repetitions of patients and the severity of needle pain according to the VAS scale were presented in **Tables 2** and **3**. The severity of needle pain and the number of uses of the same needle tip were compared. There was no correlation between the number of reuses of the same needle tip and the severity of pain (p=0.2; r=0.1).

Age (year)	55.3±11.1
Gender (Male/Female) n (%)	37/89 (29/71)
Duration of diabetes (year)	11.8±7.3
Duration of insulin use (year)	4.7±4.8
Type of insulin pen n (%)	
Conventional pen	63 (50%)
Novopen TM	34 (54%)*
Humapen TM	29 (46%)*
Disposable pen	63 (50%)
Flexpen TM	12 (19%)**
Solostar TM	17 (27%)**
Kwikpen TM	34 (54%)**
Insulin regimen n (%)	
Premix insulin	68 (54%)
Basal insulin	29 (23%)
Basal-bolus insulin	29 (23%)
Insulin dose (IU)	39.6±22.9
Number of using the same needle tip	1.76± 1.1
Intensity of needle pain	2.87±2.2
Educational status n (%)	
Primary School	65 (51.6%)
High School	25 (19.8%)
University	24 (19%)
Illiterate	12 (9.5%)
FBG (mg/dl)	177.7±72.6
HbA1c (%)	8.4±1.7
Retinopathy n (%)	42 (33.3%)
Nephropathy n (%)	24 (19%)
Neuropathy n (%)	36 (28.6%)

All parameters are given as mean±standard deviation unless otherwise stated. FBG; fasting blood glucose, HbA1c; glycated hemoglobin. * The percentage in the conventional pen group is given. ** The percentage in the disposable pen group is given.

Number of needle tip reuse	Total n (%)
1	67 (53.2)
2	39 (31)
3	11 (8.7)
4	4 (3.2)
5	3 (2.4)
6	1 (0.8)
7	1 (0.8)

Intensity of needle pain (cm)	total n
0	-
1	18
2	26
3	21
4	17
5	5
6	26
7	5
8	2
9	5
10	1

VAS: Visual Analogue Scale

Ergonomics and HbA1c

There were no patients who found the insulin pen ergonomically 'very poor'. 14.3% of the patients found the insulin pen ergonomically 'excellent'. According to the one-way ANOVA test, HbA1c values differed significantly between the four ergonomic evaluation groups (p=0.04). A post hoc analysis was performed to determine from which groups the difference originated. HbA1c values were significantly different in all groups. HbA1c values in the 'excellent' group were significantly lower than those in the other groups and HbA1c values in the 'moderate' group were significantly higher than those in the other groups (**Table 4**). Correlation analysis revealed a negative correlation between HbA1c and ergonomic satisfaction. When ergonomic satisfaction improves, HbA1c decreases (p=0.01; r=-0.2). A negative correlation was also found between FBG and ergonomic satisfaction (p=0.01; r=-0.2). A statistically significant difference was found between insulin regimens according to the ergonomic evaluation groups (p=0.0001). The rate of basal-bolus insulin regimens was significantly lower in the "excellent" group than in the other groups.

	Ergonomics				p
	Excellent (n=18)	Good (n=77)	Moderate (n=24)	Poor (n=7)	
HbA1c	8.0±1.4	8.3±1.6	9.3±1.9	8.8±1.3	0.04

SD: standard deviation; HbA1c: glycated hemoglobin

Ease of Needle Tip Replacement and HbA1c

In our study, no patient found needle tip replacement "very difficult." 34.9% of patients found it "very easy." According to the one-way ANOVA test, HbA1c values differed significantly between the four assessment groups (p=0.04). In a post hoc analysis, HbA1c values were significantly different in all groups. HbA1c values in the 'difficult' group were significantly higher than those in the other groups (Table 5). HbA1c values in the 'very easy' group were significantly lower than those of the other groups. In correlation analysis, a negative correlation was found between the ease of needle tip change and HbA1c level. The HbA1c value decreased with increasing ease of needle tip change (p=0.006; r=-0.2). When analyzing the correlation between the ease of needle tip change and FBG, a negative correlation was observed (p=0.001; r: -0.3). There was no significant difference between the groups with respect to the insulin regimen used (p=0.08).

Table 5. Comparison of HbA1c values based on ease of needle tip change assessment groups (mean±SD)

	Ease of needle tip change				P
	Very easy (n=44)	Easy (n=64)	Moderate (n=13)	Difficult (n=5)	
HbA1c	8.0±1.6	8.4±1.6	9.3±1.6	9.6±2.2	0.04

SD: standard deviation; HbA1c: glycated hemoglobin.

Ease of Reading the Dose Scale and HbA1c

7.1% of patients found the readability of the dose scale 'very difficult' and 21.4% of patients found it 'very easy'. No statistically significant relationship was found between the readability of the dose scale and HbA1c level. However, the group that perceived the readability of the dosage scale as 'easy' and 'very easy' had the lowest mean HbA1c value (8.3±1.6% and 8.3±1.7%, respectively) (p=0.53) (Table 6). No correlation was observed between the ease of reading the dosage scale and the HbA1c (p=0.21; r=-0.09) or FBG (p=0.12; r=-0.1). There was no significant difference between groups with respect to the insulin regimen used (p=0.08).

Table 6. Comparison of HbA1c values based on ease of readability of the dosage scale assessment groups (mean±SD)

	Ease of readability of the dosage scale					P
	Very easy (n=27)	Easy (n=57)	Moderate (n=22)	Difficult (n=11)	Very difficult (n=9)	
HbA1c	8.3±1.7	8.3±1.6	8.5±1.4	9.3±2.5	8.5±1.5	0.53

SD: standard deviation; HbA1c: glycated hemoglobin

Ease of Dose Selection and HbA1c

2.4% of patients found dose selection 'very difficult'. 27% found it 'very easy'. One-way ANOVA test showed that HbA1c values were significantly different between the five evaluation groups (p=0.02). In the post-hoc analysis,

HbA1c values in the 'difficult' group were significantly higher than the other groups, and HbA1c values in the 'very easy' group were significantly lower than the other 4 groups (Table 7). A negative correlation was observed between the ease of dose selection and HbA1c (p=0.01; r=-0.2) and FBG (p=0.001; r=-0.3). There was no significant difference between groups with respect to the insulin regimen used (p=0.35).

Table 7. Comparison of HbA1c values based on ease of dose selection assessment groups (mean±SD)

	Ease of dose selection					P
	Very easy (n=34)	Easy (n=65)	Moderate (n=17)	Difficult (n=7)	Very Difficult (n=3)	
HbA1c	8.1±1.7	8.3±1.5	8.6±1.8	10.5±1.7	8.4±1.4	0.02

SD: standard deviation; HbA1c: glycated hemoglobin

Ease of the Insulin Pen Use and HbA1c

One patient (0.8%) rated the use of the pen as 'very difficult'. 27.8% of patients rated the use of the pen as 'very easy'. One-way ANOVA test showed that HbA1c values differed significantly between the five assessment groups (p=0.01). Post hoc analyzes showed that HbA1c values in the 'difficult' group were significantly higher than those in the other groups (Table 8). HbA1c levels were lower in the 'very easy' group than in the 'difficult' (p=0.001), 'very difficult' (p=0.04) and 'moderate' groups (p=0.01). There was no significant difference between the 'easy' group and the 'very easy' group (p=0.09). There was a negative correlation between the ease of use of the pen and HbA1c level (p=0.02; r=-0.2). No correlation was found between ease of use and FBG value (p=0.08; r=-0.2). There was no significant difference between groups in terms of insulin regimen used (p=0.16).

Table 8. Comparison of HbA1c values based on ease of insulin pen use assessment groups (mean±SD)

	Ease of insulin pen use					P
	Very easy (n=35)	Easy (n=75)	Moderate (n=13)	Difficult (n=2)	Very Difficult (n=1)	
HbA1c	8.2±1.4	8.3±1.7	9.0±1.7	12.2±1.6	8.7±1.3	0.01

SD: standard deviation; HbA1c: glycated hemoglobin

DISCUSSION

Studies have shown that adherence to insulin therapy is low (5,6). In a study of 1099 subjects, the average adherence to insulin was 71% (5). In a systematic review of type 2 diabetics receiving insulin, adherence was 63% (6). The type of injection and patient satisfaction with therapy are important factors influencing adherence and thus glycemc control (7). After insulin pens were shown to facilitate insulin injection and increase adherence, insulin pens with different features and brands were

developed to facilitate patient use. Another issue with insulin therapy and injection is that mistakes can have serious consequences. Overdose of insulin can lead to severe hypoglycemia and coma, and underdose of insulin can lead to hyperglycemia and sometimes ketoacidosis. Considering the importance of injecting at appropriate doses and patient compliance, it is now observed that insulin pen technology is gradually developing and different types of pens are being manufactured. While some pens have a half-unit option and a memory option, others offer different color options, an 80-IU dose option, a clearly audible click sound, and low injection effort. Patient preference, availability of the pen on the market, the insulin formulation it contains, price, and physician choice determine the type of pen used (14). Studies have shown that patients prefer some insulin pens to others, and insulin pen preferences may vary from person to person (15-18). Using the insulin pen that the patient prefers and is satisfied with may positively influence treatment outcome. We confirmed this hypothesis in our study and found that the more comfortable patients are with the method of insulin injection, the more likely they are to adapt to insulin therapy, which may contribute to a decrease in HbA1c. This observation is consistent with other studies that have shown that glycemic control improves as patient satisfaction increases (12,19,20). Nicolucci A et al. (19) used the WHO -Diabetes Treatment Satisfaction Questionnaire (DTSQ) to measure satisfaction with the diabetes treatment regimen. The DTSQ score was inversely related to HbA1c levels and diabetic complications. A large cohort study of 4513 type 2 patients treated with insulin DM showed that proper pen selection and professional education resulted in higher patient satisfaction and better glycemic control. This study also showed that both better glycemic control and satisfaction with treatment can reduce body mass index (12). In the study by WK Redekop et al. (20), diabetic patients with higher HbA1c levels were less satisfied with treatment than other patients. In this study, the presence of complications was found to be associated with lower satisfaction. In our study, treatment satisfaction had a significant effect on HbA1c levels. It is well known that proper use of insulin injection techniques is important to optimize treatment efficacy and achieve better glycemic control. If the patient finds the pen to be very ergonomic, this may indicate that there are no obvious problems in holding and gripping the pen and therefore they can inject more accurately. The fact that patients find it very easy to choose a dose may have a positive impact on glycemic control by reducing the possibility of errors in dose adjustment and making dosing more accurate. If it is easy to change the needle tip while using the pen, the injection time will be shorter and patients will need less time to inject insulin. This can reduce repetitive use of

the needle tip. The ease of changing the needle tip likely contributes to treatment adherence and good glycemic control through correct injection. Correct injection is critical to achieving blood glucose goals. Failure to inject correctly will result in undesirable outcomes such as inability to deliver an adequate insulin dose, increasing pain, and tissue damage at the injection site. One of the biggest mistakes in insulin injection is the reuse of the needle tip. In our study, it was observed that about half of the patients (53.2%) discarded the needle tip after the single use as recommended. In the literature, reuse of the same needle tip for insulin injection as in our study is very common. In a study conducted in Moscow, single use of the needle was never observed, 7% of patients changed the needle every 2-3 days, 46% changed it once a week, and 23% changed it once a month (21). In the European epidemiological study of insulin technique, Strauss K et al. (22) found that a needle tip was used an average of 3.3 times. Injection pain increases when the needle tip is reused. In the study by Misnikova et al. (21) it was observed that injection site pain was more frequent when the needle tip was reused, and the risk of microbial contamination was 26.6%, even after the needle had been used once. In our study, there was a weak positive correlation between the number of times the same needle tip was reused and the severity of pain.

Our study had some limitations. This study did not compare the superiority of one insulin pen over another. In addition, the effect of patient ratings of each insulin pen group on glycemic parameters was not examined because there were not enough patients in each insulin pen group to make comparisons. Only whether patients' evaluations about the insulin pen they used affected HbA1c levels was examined. The study population was a heterogeneous group of participants that included patients who used premix as well as patients who used basal and basal-bolus insulin only. Apart from evaluating patients on treatment, other factors that may influence HbA1c levels and FBG, such as insulin dose used, number of insulin injections, diet, and physical activity, could not be studied. Although there were no patients with severe neuropathy and retinopathy in the study population, patients with neuropathy and retinopathy were not excluded when calculating the Visual Analogue Scale (VAS) score and assessing the ease of pen use and other factors. These complications may affect patients' assessment of the pen.

CONCLUSION

Our study showed that in T2DM, patients' opinions of insulin pen injection may affect the glycemic control. If patients perceive the insulin pen as easy to use and ergonomically good, this may lead to better glycemic

control. However, we did not investigate whether this situation is related to the appropriate dose of insulin injection or adherence to therapy. However, we think this could lead to new studies that involve more patients and investigate patient satisfaction and the importance of appropriate injection in insulin therapy. To demonstrate the influence of patients' opinions about the insulin pen on HbA1c levels, more comprehensive studies are needed that examine all parameters that may influence HbA1c levels.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was approved by the Clinical Researches Ethics Committee of the Kırıkkale University (Date: 17.07.2013, Decision No: 14/01).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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