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Evaluation of type 1 diabetic patients: A single center experience

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Abstract

We evaluated patients diagnosed with type 1 DM who were followed at our clinic by conducting a retrospective chart review. Medical records of a total of 147 patients with type 1 DM (70 females, 77 males) with a mean (±SD) age of 31.2±9.7 years were reviewed retrospectively. The study patients had a mean duration of follow-up of 13.9±9.5 years, mean duration of follow-up of 4±2.6 years at our clinic and a mean HbA1c value of 8.3±2.1%. Microvascular complications were recorded in medical files for 128 patients. There were 48 (37.5%) patients with at least one microvascular complication. Medical records showed that out of 128 patients, 23 (18%) had diabetic neuropathy alone, 4(3%) had diabetic retinopathy alone and 5 (4%) had diabetic nephropathy alone. Ten patients (8%) had both diabetic nephropathy and diabetic retinopathy and 6 (4.7%) patients had all three microvascular complications. No significant difference was observed between patients with or without microvascular complications in terms of HbA1c (HbA1c 8.3% versus 8.1%; p=0.85). A history of diabetic foot ulcer was present in 4 patients in the study sample (4/147=2.7% of all patients).Twenty-two (15%) patients were on insulin pump therapy during follow-up. Insulin pump users had a significantly lower HbA1c value (7.9%) compared to those not using insulin pump (8.5%) (p=0.02). At our clinic, special efforts are being made to ensure type 1 diabetic individuals have regular outpatient examinations. Despite all these measures, our patients are still far from reaching their target HbA1c values, suggesting that we have to do much more help patients achieve their glycemic goals.

Keywords: Type 1 Diabetes Mellitus (Type 1 DM), insulin pump, glycemic control, HbA1c, microvascular complications

Introduction

Type 1 Diabetes Mellitus (DM) is a chronic disease characterized by absolute insulin deficiency. Individuals are often diagnosed with this condition during childhood or young adulthood. Since these individuals spend a significant portion of their lives as diabetic patients, they face risk of developing micro- and macrovascular complications of diabetes. Maintenance of appropriate blood glucose regulation through replacement of deficient insulin and protecting the individual from diabetes complications are the major goals in the follow-up of type 1 DM [1-3]. Microvascular complications of diabetes can be avoided and even premature death due to macrovascular complications can be prevented with the best possible glucose regulation [4-5]. Many international bodies recommend targeting a HbA1c level below 7% [6,7] but unfortunately this is not a very target to achieve [8].

Two common methods are used for the treatment that relies of the principle of replacement of deficient insulin. One of these methods, the "intensive insulin therapy" generally consists of administration of 1 basal insulin and three injections of short-acting subcutaneous insulin before meals. The second method is "insulin pump therapy" that provides continuous subcutaneous insulin delivered from a reservoir in the pump and infused into the body through a needle set inserted under the patient's skin. The insulin pump allows administration of short-acting insulin before meals according to the carbohydrate content of the meal [9,10]. The dose of insulin to be infused by the insulin pump can be adjusted, offering the advantage of dosage flexibility. However, compared to conventional intensive insulin therapy, insulin pump requires multiple measurements of blood glucose and also is more costly due to its expensive equipment such as infusion set. Moreover, insulin pump therapy requires active involvement of the patient in his or her own therapy including the need to calculate the carbohydrate content of the meal, perform more frequent self-monitoring of blood glucose and adjust the insulin infusion rate to meet their needs. In theory, patients using insulin pump should have improved glucose regulation. However, failures in administration and monitoring may preclude achievement of target glucose values [11,12]. Therefore, we aimed to retrospectively review the data of type 1 DM patients using or not

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using insulin pump who are being followed at our clinic.

Material and Methods

Medical records of a total of 147 patients with type 1 DM were reviewed retrospectively.

The study was approved by the local Ethics Committee of the Medical Faculty of the Tekirdag Namik Kemal University and performed in accordance with Good Clinical Practice procedures and the current revision of the Declaration of Helsinki (No: 2020.246.11.06).

Results

Mean (±SD) age of 70 females and 77 males was 31.2±9.7 years. No difference was observed between females and males in terms of mean age and the duration of diabetes.

The mean age of patients at the time of type 1 DM diagnosis was 17.6±9.1years. The study patients had a mean duration of follow-up of 13.9±9.5 years, mean duration of follow-up of 4±2.6 years at our clinic and a mean HbA1c value of 8.3±2.1% (Table 1).

Table 1. Demographic, clinic and diabetes-related characteristics of patients with type 1 diabetes

Parameter/(unit)	Mean±Standard Deviation (SD)	Min	Max
Age (years)	31.2±9.7	17	67
Age at DM diagnosis	17.6±9.1	1	40
Duration of DM (years)	13.9±9.5	1	44
Duration of follow-up at our clinic (years)	4±2.6	1	10
HbA1c (%)	8.3±2.1	5.6	13.2

*HbA1c value is expressed as %.

Twenty-two (15%)patients were on insulin pump therapy during follow-up. Insulin pump users had a significantly lower HbA1c value (7.9%) compared to those not using insulin pump (8.5%) (p=0.02) (Table 2).

Table 2. HbA1c values in insulin pump users versus non-users

Parameter	Insulin pump use	Mean± Standard Deviation (SD)	P
HbA1c* (n=147)	Yes (n=22)	7.9±1.7	0.02
	No (n= 125)	8.5±2.3	

*HbA1c value is expressed as%.

A total of 128 patients were evaluated for microvascular complications of diabetes. While diabetic nephropathy can occur even at the onset of "microalbuminuria", patients with a glomerular filtration rate (GFR) less than 60 ml/min/1.73 m² were defined as having diabetic nephropathy in the present study. Patients with findings of proliferative or non-proliferative retinopathy included in the ocular examination records were considered as having diabetic retinopathy. Diabetic neuropathy was recorded as present or absent based on whether the patient had complained of bilateral distal symmetric sensory neuropathy. There were 48 (37.5%) patients with at least one microvascular complication. Medical records showed that out of 128 patients, 23 (18%) had diabetic neuropathy alone,4 (3%) had diabetic retinopathy alone and 5 (4%) had diabetic nephropathy alone. Ten patients (8%) had both diabetic nephropathy and diabetic retinopathy and 6 (4.7%) patients had all three microvascular complications. A history of diabetic foot ulcer was present in 4 patients in the study sample (4/147=2.7% of all patients).Patients with diabetic foot ulcer had all microvascular complications in addition to diabetic neuropathy. Although patients without microvascular complications had a lower mean HbA1c than in patients with such complications, the difference was not statistically significant (Table 3).

Table 3. HbA1c levels based on the presence or absence of microvascular complications

Parameter	Microvascular complications	Mean± Standard Deviation (SD)	P
HbA1c* (n=128)	Yes (n=48)	8.3±1.5	0.85
	No (n= 80)	8.1±1.7	

*HbA1c value is expressed as %.

Of 22 insulin pump users, 7 (31.8%) had at least one microvascular complication. Diabetic neuropathy alone was present in 6 patients and 1 patient had all three microvascular complications. The latter patient had DM for 25 years. Among 22 insulin pump users, those with microvascular complications were older, had a longer duration of diabetes and higher HbA1c levels compared to those without microvascular complications. While age and DM duration were statistically significantly different between patients with or without microvascular complications, HbA1c levels were not significantly different (Table 4).

Table 4. Clinical features of 22 insulin pump users with or without microvascular complications

Parameters	Age (years)	DM duration (years)	HbA1c (%)
Microvascular complications present (n=7)	45.3±12.7	27.1±10.1	8.3±1.5
Microvascular complications absent (n=15)	29.9±7.3	12.8±4.8	7.4±1.4
p	0.02	<0.01	0.17

*HbA1c value is expressed as %.

Among 48 patients with microvascular complications, mean HbA1c level was 8.9±2 % in 41 patients not on insulin pump treatment and 8.3±1.5 % in 7 patients on insulin pump treatment, (p=0.13).

"Regular follow-up patients" were defined as those with HbA1c follow-up visits at least every 3 months and "irregular follow-up patients" were those who had follow-up visits at an interval of more than 3 months or less than 4 HbA1c visits per year. Patients with "regular follow-up" appeared to have a lower mean HbA1c value versus "irregular follow-up" patients but the difference did not reach statistical significance (Table5).

Table 5. HbA1c levels according to the follow-up status

Parameters	Follow-up Status	Mean± Standard Deviation (SD)	p
HbA1c (n=147)	Regular (n=76)	8.2±2.4	0.14
	Irregular (n=71)	8.5±1.9	

*HbA1c value is expressed as%

Discussion

Patients with type 1 DM are at risk for diabetes complications because the underlying pathophysiology is absolute insulin deficiency and the diagnosis occurs at an early age. Poorly controlled diabetes has been recognized to be a risk factor for microvascular complications in type 1 diabetic patients since the Diabetes Control and Complications Trial (DCCT) [1,2]. Although all physicians engaged in diabetes follow-up strive to achieve good glycemic control, unfortunately the outcomes fall short of expectations. The major finding of the present study was that patients with type 1 DM failed to achieve the desired HbA1c values. However, our results are consistent with those reported by international cohort studies [13-16]. Interestingly, median HbA1c values which were retrospectively reviewed in a New Zealand study published in 2020 closely match our results [17]. Failure to attain target HbA1c values as observed in the current study may be associated with many physician- or patient related factors. Patient-related factors include poor adherence to insulin therapy leading to irregular insulin injections and even missing some doses, inadequate administration of insulin doses due to fear of hypoglycemia and non-compliance to exercise and diet. Physician-related factors include lack of proper education of diabetic patient by the healthcare provider on the physiopathology of diabetes, management of hypo- and hyperglycemia and diabetes complications as well as low frequency of patient follow-up visits and limited time dedicated for an individual. Being far away from target HbA1c values in our patients indicates that we need to take more stringent measures to improve educational and follow-up activities for type 1 DM patients at our clinic. Our findings underscore the need for tighter glycemic control in both patients receiving intensive therapy and patients using insulin pump to attain glycemic targets and type 1 diabetic population should be followed more closely and more frequently than type 2 diabetic population [18]. Unfortunately, little information on hypoglycemic episodes was included in the medical records of our patients. This is one of the most important shortcomings that we face during follow-up of our patients. Hypoglycemic episodes should be investigated and recorded at each visit for all patients. We occasionally observe elevated glucose values in type 1 diabetic population due to fear of "hypoglycemia". It would be possible for us to reduce the development of chronic complications by providing more comprehensive patient education on the management of hypoglycemic episodes and setting more stringent glycemic targets in type 1 diabetic patients [19-22].

Due to the retrospective nature of our study, the patients could not be assessed for macrovascular complications of diabetes. While a total of 147 patients were evaluated, only 128 of them were questioned with regard to microvascular complications as noted in their records. Thus, a microvascular complication rate of 37.5% (48/128) may not reflect the true prevalence of microvascular complications in our sample. Based on our findings, diabetic neuropathy alone was present in 18%, diabetic retinopathy alone in 3%, diabetic nephropathy alone in 4% of the patients; 8% of patients had both diabetic nephropathy and diabetic retinopathy and4.7% of patients had all 3 microvascular complications. Thus, 22.5% of the patients had symptoms of neuropathy, 15.7% had symptoms of retinopathy and 17.7% had symptoms of nephropathy. These figures are consistent with the rates of microvascular complications reported for patients with poorly controlled diabetes [12,15,19,23]. However, such high rates might have been detected in our study due to inclusion of patients evaluated for microvascular complications, particularly neuropathy. Furthermore, since our outpatient clinic is part of a tertiary health-care facility, more complicated patients may have presented for medical help.

Although the study patients with microvascular complications had relatively low HbA1c levels, statistical significance was not observed. However, the fact that HbA1c levels are far away from target glycemic goals in both groups suggests that the subset of patients without microvascular complications are at risk for developing such complications. The DCCT trial was the first and most important study to show the significance of good glycemic control to both prevent the appearance (primary prevention) and the progression of microvascular complications (secondary intervention) in type 1 diabetic individuals and later studies corroborated these findings [1,2,3,19]. The prevalence of microvascular complications may vary according to the time lived with diabetes and whether the glycemic control is good or poor for an individual patient. Also, the criteria used for defining neuropathy, retinopathy and nephropathy may result in variable rates.

In the current study, microvascular complications were present in 7 of 22 patients on insulin pump therapy. Among those patients with microvascular complications, 6 had only diabetic neuropathy with no nephropathy or retinopathy. One patient with all three microvascular complications was both older and had a much longer diabetes duration compared to other patients. Patients who had microvascular complications were older and had a longer duration of diabetes than those who did not. While slightly elevated HbA1c values were found in individuals with microvascular complications, the elevation was not statistically significant. This suggests that HbA1c is not the sole factor involved in the development of complications in type 1 diabetes but the duration of diabetes may also have an impact .

Moreover, since our study was of retrospective nature, it is not known how long these patients have been using an insulin pump and whether the insulin pump was present before or after complications occurred. In addition, slightly greater HbA1c levels may have been found in individuals with chronic complications, since slightlyhigh average blood glucose levels are desired in such patients in order to protect them from hypoglycemia. Further prospective studies are needed to demonstrate the impact of the insulin pump on the occurrence of chronic complications of diabetes.

In our study, "regular follow-up patients" were defined as those with HbA1c follow-up visits every 3 months and no significant

difference was found between these patients and “irregular follow-up patients” with respect to HbA1c values. This suggests that HbA1c follow-up visits every 3 months are not sufficient alone particularly in type 1 diabetic patients. It also suggests that all patients with type 1 diabetes should be more closely followed than type 2 diabetic patients and possibly more frequently (at an interval of less than 3 months) until they develop adequate diabetes self-management skills.

Another important finding of this study was that patients using insulin pump had relatively better HbA1c values when compared with other patients. This may be explained by the fact that insulin pump users perform more frequent glucose measurements and are able to increase or reduce their bolus insulin doses in a flexible manner based on carbohydrate counting. It is known that insulin pump has positive effects on "hypoglycemia, glycemic fluctuation and quality of life" in individuals with type 1 DM. One of the limitations of this study includes its retrospective nature and lack of detailed information in patient files, which precluded assessment of these important parameters.

However, this patient group is also far from being at their target goals, suggesting that a more satisfactory and closer follow-up is needed for insulin pump users [10,11,24].

Conclusion

At our clinic, special efforts are being made to ensure type 1 diabetic individuals have regular outpatient examinations. In addition, patients are educated on carbohydrate counting and insulin pump use is promoted at follow-up visits. Also, individuals who wish to switch to insulin pump treatment are supported by a physician, a dietitian and a diabetes education nurse. Despite all these measures, our patients are still far from reaching their target HbA1c values, suggesting that we have to do much more help patients achieve their glycemic goals.

Conflict of interests
The authors declare that they have no competing interest

Financial Disclosure
All authors declare no financial support.

Ethical approval
The study protocol was approved by the Tekirdag Namik Kemal University Ethics Committee (No: 2020.246.11.06)

Note
The results of this study were reported as oral presentation at the Post-Graduate Training Course, Endo Course 4 held between October 4-6, 2019.

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