Benefits of Using the i-Port System on Insulin-Treated Patients
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ABSTRACT
Background. Insulin-treated patients demonstrate low adherence to insulin injections, which results in poor glycemic control. The i-Port Advance is a new advanced injection method. Our aim was to evaluate patient satisfaction, glycemic control, and adherence with this device.

Methodology. This prospective study examined i-Port use in 55 insulin-treated patients. Baseline characteristics and Diabetes Treatment Satisfaction Questionnaire status (DTSQs) scores were collected at baseline and at the end of the follow-up period. All patients were trained to use the i-Port. Patients were divided into two groups: regular users of the i-Port, who used it for ≥3 months, and irregular users, who used it for <3 months. Local complications during use of the i-Port were recorded.

Results. Of the 55 patients, 92.7% had type 1 diabetes, the mean age was 14.96 ± 8.95 years, and 92.7% used an insulin pen. The patients were divided into 27 regular users and 28 irregular users. Irregular users had a longer duration of diabetes (P = 0.901) at baseline compared to regular users, were less likely to report noncompliance with insulin usage (P = 0.338), were more likely to self-inject insulin (P = 0.038), and had a lower A1C (P = 0.056). There were no statistical differences between groups in mean DTSQs treatment satisfaction scores or mean glycemic control scores. At the end of the follow-up period, regular i-Port usage improved compliance with insulin usage (P = 0.028), reduced diabetes-related hospitalizations (P <0.001), and reduced the frequency of hypoglycemia (P = 0.184). Scarring at the i-Port site was the most common complication.

Conclusion. Regular i-Port usage improved compliance and decreased hospitalizations and hypoglycemic episodes, with a nonsignificant 0.73% reduction in A1C.

In recent decades, there has been an increase in the number of people with diabetes and related complications, which are a significant cause of morbidity and mortality (1). However, there have also been great advances in available types of insulin and methods of delivery (2). All people with type 1 diabetes need insulin, and most of those with type 2 diabetes, especially those with a long duration of disease, will eventually need insulin. A recent Centers for Disease Control and Prevention report estimates that 17.8 and 13% of people with type 2 diabetes in the United States were on insulin and insulin/oral agent combination therapy, respectively (3).

Subcutaneous injection is considered the most widely used method to deliver insulin (4), despite numerous barriers to its use, including potential pain, patients’ avoidance due to

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injection-related anxiety or phobias, concerns about the potential eventual need for increased injection frequency, and a substantial negative impact on quality of life (5,6). All of these issues can become barriers to patients’ therapy adherence, which can result in poor glycemic control (7). A recent study (8) suggested that 14.3% of patients with type 1 diabetes and 28.8% of those with type 2 diabetes had low adherence to insulin therapy (8).

These difficulties motivate researchers to develop alternative and appropriate methods to improve patients’ acceptance of and adherence to insulin therapy and to facilitate insulin injections while maintaining accurate delivery. One of these advanced injection methods is the i-Port Advance injection port (Medtronic MiniMed, Northridge, Calif.), which provides a comfortable yet dependable way to inject insulin that allows patients to take multiple daily subcutaneous injections throughout 3 days without having to puncture their skin for each dose. For patients who are using a multiple daily injection insulin regimen, using the i-Port system can reduce the number of skin punctures from as many as 150 to just 10 over 1 month. In addition, patients are not required to remove the i-Port Advance for daily activities (9).

The purpose of this study was to evaluate patient satisfaction when using the i-Port Advance. We also examined the effects of this device on patient acceptance of and adherence to insulin therapy and on glycemic control.

Methodology
This prospective study was conducted at the Diabetes and Endocrine Center at Prince Mansour Military Hospital in Taif, Saudi Arabia. Patients with either type 1 or type 2 diabetes who had a routine visit to the Diabetes Educator Clinic from June 2015 to June 2016 were asked to participate. Data were collected through a formal interview with each patient. Participants gave verbal consent. Patients with gestational diabetes and those with existing psychiatric disorders were excluded.

The researchers obtained baseline characteristics and measurements for each participant. Laboratory data were collected from each patient’s electronic medical records. All patients were educated and trained to use the i-Port Advance injection port, which includes a built-in inserter and allows for quick and virtually painless application. Only a soft flexible tube called a cannula stays under the skin. Once the port is applied, patients inject themselves with an insulin pen through the port instead of through the skin (9).

Patients were identified by their names and medical record numbers. All patients were interviewed using a questionnaire to collect personal data and baseline characteristics. This questionnaire was tested with 10 patients before the data collection phase of the study to check for errors, ambiguities, and redundancies.

The participating patients’ satisfaction levels were assessed using the Arabic version of the Diabetes Treatment Satisfaction Questionnaire status (DTSQs) (10). The DTSQs is an eight-item questionnaire that has been used in a number of clinical trials and in routine clinical practice to determine patient satisfaction with their diabetes medications. Each item was scored on a 6-point Likert scale. Scores on items 1, 4, 5, 6, 7, and 8 were summed to form a treatment satisfaction score ranging from 0 to 36. A score of 0 indicated the least satisfaction with treatment, with higher scores indicating greater satisfaction to a maximum satisfaction score of 36. Items 2 and 3 of the questionnaire were summed to form a glycemic control score ranging from 0 to 12. Each of these items is rated from 0 to indicate “none of the time” to 6 to indicate “most of the time,” with lower scores indicating blood glucose levels closer to a normal range (11).

Researchers followed up with all of the participants within a few weeks to a few months of their initial visit and asked about their i-Port use experience and duration. Participants were then divided into two groups: regular (continuous) users of the i-Port for ≥3 months (group A) and irregular (discontinuous) users (group B). Participants in both groups were asked to complete the DTSQs again and were asked about the duration of their use of the i-Port and the local complications they experienced during and after i-Port use. Any patient who reported missing an insulin injection for any cause was considered to be noncompliant.

Data were collected in an Excel spreadsheet (Microsoft Corp., Columbia, Md.) and analyzed using SPSS version 20 (IBM Corp., Chicago, Ill.). Means and SDs were used to present scale data, and frequency and percentages were used to present categorical data. The $\chi^2$ test was used to assess the relationship between variables, and a $t$ test was used to compare the means in the analysis. We considered $P \leq 0.05$ to be statistically significant.

Results
A total of 55 patients comprising 25 males and 30 females were included, and 92.7% of them were using an insulin pen. A majority were also patients with type 1 diabetes (92.7%). Although the mean duration of diabetes was 4.6 ± 4.25 years, the mean A1C was 9.54 ± 1.81%, with 45.5% reporting noncompliance with insulin doses. Most participants at baseline had had a diabetes-related hospitalization in the previous 3 months. Fear of needles accounted for only 9.1% of insulin noncompliance (Table 1).

At baseline, 27 patients were regular users of the i-Port, and 28 patients were irregular users. The mean duration of i-Port usage was 7.1 months (SD 3.6 months) among the regular users and 0.6 months (SD 0.35 months) among irregular users. At baseline, there was no statistically significant difference between
the two groups regarding mean age ($P = 0.812$), sex ($P = 0.549$), type of diabetes ($P = 0.681$), or mean diabetes duration ($P = 0.901$). Moreover, mean A1C ($P = 0.056$), diabetes-related hospitalization in the previous 3 months ($P = 0.189$), number of hospitalizations ($P = 0.976$), and hypoglycemia frequency ($P = 0.146$) were not significantly different between groups.

At baseline, regular users were more likely to report noncompliance with insulin compared to irregular users, with a fear of needles being the main reason, but the difference was not statistically significant ($P = 0.338$ and $P = 0.328$, respectively). On the other hand, insulin self-injections by patients were higher among irregular users (48.1%) than regular users (25.9%) ($P = 0.038$). At baseline, the mean DTSQs scores were higher among irregular users (31.2%) than regular users (28.9%), whereas the mean glycemic control score was higher among regular users (7.3%) than irregular users (6.7%), but without statistical significance ($P = 0.159$ and $P = 0.380$, respectively) (Table 2).

We compared the characteristics of the regular users alone at baseline and at the end of the follow-up period. At the end of the follow-up period, there was a statistically significant decrease in the mean number of missed insulin doses ($P = 0.032$), patients were more likely to report compliance with insulin ($P = 0.028$), and the number of diabetes-related hospitalizations decreased ($P < 0.001$). We found no statistically significant difference between baseline and the end of follow-up with regard to the DTSQs treatment satisfaction and glycemic control scores, although the mean A1C was lower at the end of follow-up than at baseline. Also, frequent hypoglycemia (weekly or more often) was higher at baseline than at the end of follow-up, but the difference was not statistically significant (Table 3). The most common local complication during and after the i-Port use was scarring (60%), and the least common was swelling at the i-Port site (5.5%) (Figure 1).

**Discussion**

Our study mainly included young patients with short-duration type 1 diabetes who used insulin pens and were likely to report noncompliance with insulin and to have uncontrolled diabetes. The regular use of the i-Port resulted in a nonsignificant improvement of A1C and decrease in the frequency of the hypoglycemia. Compared to baseline, regular i-Port users at the end of the follow-up period were more likely to report compliance with insulin and to have fewer diabetes-related hospitalizations, which were statistically significant differences.

For the whole cohort, only 36.4% of the patients reported self-injection of insulin at baseline. Regular users of i-Port at baseline were less likely than irregular users to report self-injecting, but at the end of the follow-up period, regular users were twice as likely to self-inject insulin and had a 0.73% improvement in A1C. This

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**TABLE 1. Baseline Characteristics of the Whole Cohort**

| Patients, n | 55 |
|-------------|----|
| Age, years, mean (SD) | 14.96 (8.95) |
| Male, n (%) | 25 (45.5) |
| Female, n (%) | 30 (54.5) |
| Type 1 diabetes, n (%) | 51 (92.7) |
| Type 2 diabetes, n (%) | 4 (7.3) |
| Diabetes duration, years, mean (SD) | 4.6 (4.25) |
| A1C, %, mean (SD) | 9.54 (1.81) |
| Diabetes-related hospitalization in the previous 3 months, % | 59.3 |
| Number of hospitalizations, mean (SD) | 1.2 (1.64) |

**Frequency of hypoglycemia**

| Daily, % | 27.3 |
| Weekly, % | 32.7 |
| Monthly, % | 1.8 |
| Rarely, % | 38.2 |

**Insulin**

| Insulin pen, % | 92.7 |
| Insulin vial, % | 7.3 |
| Insulin injected by patient, % | 36.4 |
| Insulin injected by parent, % | 41.8 |
| Insulin injected by either parent or patient, % | 20 |
| Insulin injected by others, % | 1.8 |
| Noncompliant with insulin, % | 45.5 |
| Number of missed insulin doses in the previous 3 months, mean (SD) | 1.2 (1.79) |

**Reasons for insulin noncompliance**

| Forget to inject, % | 58.2 |
| Fear of needles, % | 9.1 |
| Oversleeping, % | 12.7 |
| Unavailable insulin kits, % | 1.8 |
improvement was most likely due to psychosocial effects given that many of the patients at baseline reported fear of needles as a reason for noncompliance. Also, when compared to baseline, i-Port regular users at the end of the follow-up period were more likely to report compliance with insulin, which resulted in better metabolic control with fewer diabetes-related hospitalizations. Moreover, a previous study (12) showed that self-efficacy and care correlated with better glycemic control, and our study showed that regular i-Port users were more likely to report self-injecting insulin and had a slight improvement in their treatment satisfaction score.

At baseline, 50% of the regular users reported noncompliance with insulin, and 14.8% reported a fear of needles as the cause. At the end of follow-up, 11.1% reported noncompliance with insulin. This resulted in
fewer diabetes-related hospitalizations among the regular users at the end of the follow-up period (7.4%) compared to baseline (59.3%). A previous study showed that poor insulin adherence is the main cause for recurrent hospitalizations for diabetes ketoacidosis (13).

Given the observed improvement in insulin compliance in our study and the recent advancements in glucose monitoring technology, we anticipate that patients will become more proactive with their glucose readings, which will ultimately improve their clinical and biochemical outcomes. However, a larger study would be needed to evaluate this.

Local complications at the site of the i-Port insertion were common, which may explain the small, nonsignificant improvement in treatment satisfaction despite the lower rates of hospitalization and hypoglycemia observed among regular i-Port users at the end of the follow-up period. Scarring at the site of i-Port usage was the most common side effect and was mainly due to skin irritation at the insertion site. Most of these occurrences were mild and self-limited and were completely resolved after changing the insertion site without any need for further evaluation.

The weaknesses of our study include its small sample size and short follow-up duration and the fact that it involved a single center. Its strengths include the prospective nature of the study and the novelty given the limited published data about i-Port usage. We recommend a larger prospective study for selected insulin-dependent patients who report poor adherence to insulin because of a fear of needles.

**Conclusion**

Patients in our study were mainly adolescents with poorly controlled type 1 diabetes, a majority of whom reported noncompliance with insulin and frequent diabetes-related hospitalizations. Regular i-Port usage improved compliance with insulin and self-care and resulted in lower rates of diabetes-related hospitalization and hypoglycemia, as well as a 0.73% reduction in A1C. Our study suggests that young patients with a shorter duration of diabetes for whom insulin is injected by a parent were more likely to benefit from using the i-Port Advance system.

**Duality of Interest**

No potential conflicts of interest relevant to this article were reported.

**Author Contributions**

A.M.K. and K.A.A. contributed equally to this work in designing and carrying out the reported study, analyzing the data, and writing the article. K.A.A. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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