

Impact of Pharmacist Intervention on Appropriate Insulin Pen Use in Older Patients with Type 2 Diabetes Mellitus in a Rural Area in Iran

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ABSTRACT

Objective: The aim of this study was to evaluate the impact of pharmacist-conducted educational intervention on reducing errors related to inappropriate insulin pen use.

Methods: This was a prospective, before-after study with an educational intervention component. The study was conducted on 122 elderly diabetic patients. Data were collected through interviews using researcher-administered questionnaires as well as patients' medical records. Patients were asked about the preparation, injection, and storage techniques, they followed when using insulin pens. Blood glucose parameters were extracted from laboratory records. After the detection of errors, patients and their caregivers were instructed about the insulin pen use by the pharmacist. Patients were reevaluated after 12 weeks.

Findings: Patients' mean age was 67.2 ± 3.5 with male: female ratio of 71:51. Mean diabetes duration was 7.1 ± 2.8 years. Fifty-four patients (44.2%) stated that they had received instructions for insulin pen use previously. The majority of this group (24 cases, 44.4%) reported that the instructions were given by a pharmacist. The mean number of errors decreased from 3.99 ± 0.22 errors per patient to 1.49 ± 0.13 errors (odds ratio: 0.28, 95% confidence interval: 0.23–0.33, $P < 0.05$). Of eleven evaluated insulin pen-related medication error items, nine items experienced a significant decrease after patient education. Fasting plasma glucose (FPG) levels decreased significantly from 161.7 ± 12.5 to 147.3 ± 13.1 mg/dL ($P < 0.05$). However, glycated hemoglobin levels did not change significantly after 3 months ($P = 0.18$). Controlled FPG had a significant rise from 45% before education to 63.9% postintervention ($P < 0.05$).

Conclusion: Pharmacists can play an important role in safe and efficient use of insulin pen in elderly diabetic patients by minimizing the likelihood of medication errors associated with insulin pen use.

KEYWORDS: *Diabetes mellitus, Insulin pen, medication error, pharmacist intervention*

Received: November 2016.

Accepted: February 2017.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) which is the most common type of diabetes occurs as a result of hyperglycemia associated with increased insulin resistance in body tissues. It is a frequently encountered condition among elderly, however, it is usually poorly controlled among geriatric diabetic patients.^[1,2] In the United States, patients over 60 years of age constitute more than 40% of the diabetic population.^[3] Geriatric patients are particularly at higher risk, especially those

with low literacy and knowledge of self-care to control their blood glucose levels.^[4] Poor glycemic control in these patients may stem from lack of literacy, cognitive impairment, poor vision, and hearing defects.^[5]

In rural areas of developing countries, the importance of glycemic control in geriatric patients is assumed to

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Access this article online

Quick Response Code:



Website: www.jrpp.net

DOI: 10.4103/jrpp.JRPP_16_151

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How to cite this article: Forough AS, Esfahani PR. Impact of pharmacist intervention on appropriate insulin pen use in older patients with type 2 diabetes mellitus in a rural area in Iran. *J Res Pharm Pract* 2017;6:114-9.

be more crucial as the rate of low literacy is relatively higher than urban areas,^[6] whereas, access to optimum health-care services and patient education is limited.

One of the strategies in diabetes management is insulin therapy. Despite its great importance in diabetes care, The Institute for Safe Medication Practices (ISMP) categorizes insulin among high-alert medications.^[7] Insulin-related medication errors that are frequently encountered in hospital settings pose a risk for serious damage to patients and even can be fatal.^[8] In a previous study, Milligan *et al.* evaluated adverse drug events in elderly with diabetes in the nursing home setting during a 5-year period. In this study, a total of 684 insulin-related adverse events were reported while 84 incidents were due to oral antidiabetic agents. Incorrect or unclear dose was the main type of error according to this study.^[9]

Insulin is supplied as two dosage forms of conventional vials and pens in Iran.^[10] Insulin pens have been shown to have advantages over conventional insulin vials, including more convenient delivery and simpler use, especially in specific populations such as elderly, accurate dosing, less pain, better quality of life, and better compliance with insulin regimen.^[11] Patients have reported more satisfaction and persistence in insulin therapy at home when treated with insulin pens.^[12] Moreover, another study which was conducted on elderly patients with visual and motor disabilities who needed assistance to prepare and administer their insulin revealed that more disabled elderly patients could independently inject their insulin using insulin pens rather than conventional vials and syringes (53% vs. 20%).^[13] This is an important consideration because it has been proven that one of the key factors in long-term management of diabetes is patient adherence to antihyperglycemic therapy.^[14] Despite their greater convenience, medication errors can still occur by using insulin pens, especially when the patients are not properly instructed about their method of use.

The American Diabetes Association has stated that to optimize the medical care of diabetic patients, an efficient collaboration is required among health-care professionals, including physicians, nurses, dietitians, pharmacists, and mental health professionals.^[15]

The aim of this study was to evaluate the impact of pharmacist-conducted educational intervention on reducing errors that are related to inappropriate preparation, administration, and storage of insulin pens, and its effect on glycemic control of elderly patients in a rural area in Iran with T2DM who were prescribed an insulin pen.

METHODS

The present study is a single-center, prospective before-after interventional study which was conducted from January 2015 to March 2015 in Amiral Momenin General Hospital, Khodabandeh, Iran. The study was approved by Amiral Momenin Hospital's Ethics Committee (Approval No.: 16766). All 149 outpatients with 60 years of age or above who were diagnosed with T2DM and/or their carers who were prescribed an insulin pen in any type or formulation were considered for inclusion. Only patients who visited the hospital's outpatient department were selected. After exclusion of patients hospitalized after medical examination, and patients who were unable to give informed consent or did not agree to participate, the final evaluation was performed on 122 patients. Before the study, all patients provided their written informed consent to participate in interviews, educational sessions, and follow-ups. Patients were reassured about the confidentiality of the study. Initially, a questionnaire together with an interview was used for data collection. Patients or their carers were asked about the preparation and injection techniques they followed when using their insulin pen as well as storage conditions. Blood glucose parameters (e.g., fasting plasma glucose, glycated hemoglobin [HbA1c]) were also extracted from their laboratory records. A complete history of patients' medications was taken by the pharmacist. The correct use of pen according to the physician instruction and/or manufacturer was checked as well. Eleven items were assessed based on patient/carer reports to evaluate the appropriateness of the insulin pen use and detect potential errors. The errors include multiple use of a needle, incorrect insulin pen type (differing from the prescribed pen by the physician), incorrect dosing, incorrect time of administration, blocked needle, not to roll the insulin pen before use, sharing insulin pen with other individuals, not to detach the needle immediately after injection, storage in refrigerator, incorrect injection angle, and the sufficient length of time needed to remain the needle in the injection site to ensure delivery of the entire dose. After detection of existing errors in insulin pen administration, patients and/or their caregivers were instructed about the insulin pen use by the pharmacist. An informative illustrated pamphlet was also provided for the patients. These pamphlets contained instructions on proper preparation, administration, and storage of insulin pens in lay language. The pamphlets were written in Persian, and their content was reviewed and approved by a clinical pharmacy specialist. After 12 weeks, the enrolled patients were evaluated again in terms of insulin pen preparation and administration methods and their blood glucose parameters. The intervention was made for

insulin pen only, and patients continued on their other antidiabetic agents as prescribed previously; however, in case that a serious or life-threatening interaction was detected between patient's medications and insulin, the pharmacist was responsible to inform the physician in charge about the interaction immediately.

Descriptive statistical analysis (e.g., percentages and frequencies) was used for demographic data. Chi-square test was used to find any difference before and after patient education. Data were analyzed by SPSS® software (SPSS Inc., Chicago, IL) version 16. $P < 0.05$ was considered statistically significant.

RESULTS

One hundred and forty-nine outpatients on insulin pen who visited the hospital's outpatient clinic were considered for inclusion. After applying the exclusion criteria, the final evaluation was performed on 122 patients with an average age of 67.2 ± 3.5 and male:female ratio of 71:51. Mean body mass index of the patients was 26.6 ± 1.9 with mean diabetes duration of 7.1 ± 2.8 years. Regarding the educational status of the patients, 12 (9.8%) were illiterate while 44 (36.0%), 59 (48.3%), and 7 (5.7%) had elementary school, high school, and university education, respectively.

Fifty-four patients (44.2%) stated that they had received instructions for insulin pen use previously. The majority of this group (24 cases, 44.4%) of patients reported that they had received instructions from their pharmacists while 19 (35.2%) patients were educated by a nurse and 11 cases (20.4%) were instructed by physicians. Five patients were educated by other health-care professionals (e.g., paramedics).

During the initial phase of the study, a total of 487 insulin pen-related errors were detected. This figure experienced a considerable decline after education to 182 errors. The mean number of errors decreased from 3.99 ± 0.22 errors

per patient to 1.49 ± 0.13 errors per patient (odds ratio: 0.28, 95% confidence interval: 0.23–0.33, $P < 0.05$).

Results of the changes in the rates of errors associated with improper use of insulin pen by patients before and after pharmacist's educational intervention are demonstrated in Table 1.

Comparing patients' blood glucose parameters (last fasting blood glucose [FBG] read before intervention vs. 12 weeks after educational intervention) demonstrated a significant decline in FBG levels which were found to be 161.7 ± 12.5 and 147.3 ± 13.1 mg/dL pre- and post-intervention, respectively ($P < 0.05$). However, laboratory data analysis showed that HbA1c levels did not significantly change ($8.1\% \pm 0.7\%$ – $7.6\% \pm 0.4$, $P = 0.18$) after 3 months. The rate of controlled FBG significantly increased from 45% before education to 63.9% after education ($P < 0.05$). No contraindication or serious interaction was observed between insulin and other medications received by the patients during the study period.

DISCUSSION

This study assessed the impact of pharmacist-conducted education on appropriate insulin pen use among elderly diabetic patients in a rural area. The findings of our study indicate that giving complete instructions to patients improved insulin pen use, and decreased the rate of errors associated with inappropriate use of insulin pens significantly.

Despite the efforts in health-care systems to minimize the occurrence of medication errors, insulin is still considered among high-alert medications requiring extra attention.^[8] Results of a previous investigation among insulin pen users showed that in 75% of the patients, the method of insulin pen use was not in accordance with manufacturer's instructions in terms of proper administration and storage.^[16] Therefore, coordination

Table 1: Rate of incorrect insulin pen use among patients before and after educational intervention

Errors in insulin pen use	Before intervention	After intervention	P
Multiple use of a needle	85 (69.6)	49 (40.1)	<0.05
Incorrect type of insulin pen	1 (0.8)	0	0.15
Incorrect dose	22 (18.0)	9 (7.4)	<0.01
Incorrect time of administration	32 (26.2)	6 (4.9)	<0.01
Blocked needle	3 (2.45)	0	<0.05
Rolling insulin pen before use	23 (18.8)	70 (57.3)	<0.05
Sharing insulin pen with other individuals	2 (1.6)	0	0.16
Detaching needle immediately after use	42 (34.4)	97 (79.5)	<0.01
Storage in refrigerator before opening the insulin pack	83 (68.0)	120 (98.3)	<0.01
Incorrect injection angle	33 (27.0)	5 (4.0)	<0.01
Remaining needle within the injection site for 5-6 s	31 (25.4)	88 (72.1)	<0.01

Data are presented as n (%) of participants

between health-care professionals and patients for rational use of antihyperglycemic agents can be of great importance in this case.^[9] The majority of studies around appropriate insulin pen use have been performed on hospitalized patients while information about the correct use of insulin pen among outpatients in developing countries is scarce. Mitchell *et al.* evaluated the effect of educating hospitalized patients about insulin pen usage by pharmacists or nurses. Their findings suggested that an initial education of insulin pen use results in significantly higher rates of correct usage.^[17] Another study which assessed pharmacists' role in optimizing insulin use in hospital setting indicated that pharmacist involvement can reduce the occurrence of medication errors in prescription, transcription, dispensing, and administration stage.^[18] Pharmacist intervention not only may reduce the chance of medication errors through diabetes management process but also has been shown to lessen the duration of hospitalization as well as both hyperglycemic and hypoglycemic events.^[19]

More than half of the patients in the present investigation reported that they had not received an initial education about the correct method of use for insulin pens which may be one of the factors leading to a high error rate of 3.99 ± 0.22 errors per patient.

In the current study, patient education reduced the number of insulin pen-related errors from 487 to 182 cases (3.99 ± 0.22 errors per patient to 1.49 ± 0.13). Despite this considerable decline in number of errors, this figure still remains high. There may be several factors contributing to this finding. First, more than 45% of the participants in this study were either illiterate or had only primary school education. As shown by a study, low literate patients are more than three times less likely to be adherent to their pharmacotherapy regimens.^[20] The results of another study which evaluated the health literacy of diabetic patients showed that patient with low health knowledge are more susceptible to poor glycemic control and are more likely to develop retinopathy due to diabetes.^[21]

Conventional beliefs among elderly patients, especially in rural areas may also affect their attitudes toward their antidiabetic therapy. According to one study, low medication adherence is associated with patients' negative attitudes about their medications.^[22] This is particularly important in underdeveloped areas where the substitution of more scientific-based medical therapies with alternative therapies (e.g., medicinal herbs, spiritual therapies) is frequently encountered. Since the method of insulin delivery with insulin pens is relatively new in such regions, it may not be easily accepted by the recipients.

Another important factor regarding the selection of elderly people in this study was that aside from low educational status of this subset of population in rural areas, they can be more susceptible to the probable consequences of inappropriate insulin pen use because of higher possibility of memory loss, impaired cognitive functions, or poor vision in elderly. Furthermore, it has been reported that diabetes itself may cause cognitive dysfunction.^[23]

The rate of errors after intervention still remained considerably high even though the educational intervention led to a significant drop in the rate of errors associated with insulin pen use in most of the error categories. This necessitates a complete assessment to recognize reasons behind this high rate of errors.

Other interventions can be used to improve patients' compliance to instructions given by their health-care professionals, continuous patient monitoring (e.g., through telephone calls, message reminders),^[24,25] and increasing patient health knowledge can be one of the targets in this regard.

In the present study, multiple use of insulin pen needle constituted the largest proportion of detected errors with nearly 70%. Although lack of knowledge can be the main reason for this issue, some patients stated that they tend to use the needles for several times due to cost considerations.

Moreover, in two cases, mutual use of a single insulin pen was observed which was completely resolved after education. Unfortunately, this type of error is even observed in hospital settings when insulin administration is performed by health-care professionals. Previously, the Food and Drug Administration, Centers for Disease Control, and the ISMP have advised hospitals about the risks of sharing insulin pens among patients^[7] such as transmission of blood-borne disease.^[26]

Current findings indicated that patients' FBG had a significant decline after patient education from 161.7 ± 12.5 to 147.3 ± 13.1 mg/dL. Several items can play a part in achieving this improvement. First, incorrect insulin doses received by the patients were detected by pharmacist throughout the study and were corrected. Hence, in cases that patients were receiving lower doses of insulin than what was ordered by their physician, these dose corrections may directly influence their blood sugar levels. On the other hand, in three cases, patients were injecting their insulin pen without being aware that the attached needle was blocked. Taking into consideration that each needle was used for multiple times in many of these patients, the effect of this error on glycemic control of patients becomes even more concerning. After

pharmacist instructions, no blocked needle cases were encountered after 3 months.

In addition, during the initial assessment of patients, only 25% of patients were aware about sufficient length of time after injection to ensure complete dose delivery. This means that the majority of patients did not receive the complete dose before education. The significant improvement in this figure from 25% to 72% may have positively affected the blood glucose control as well.

Unlike FBG levels, HbA1c did not show a significant change in this study ($P = 0.18$). Since this study was conducted during a relatively short period, it was not possible to assess long-term impact of patient education about insulin pen use on HbA1c levels although 3 months can be assumed long enough to observe changes in HbA1c levels. We were not able to extend the duration of study for more than 3 months because of the seasonal immigration of many people in this region which could have made the follow-up assessment hard to track or impossible for the investigator. On the other hand, measurement of HbA1c is not considered appropriate within 6 weeks from the first measurement if there has been a change in patient's diet or treatment.^[27] Since we were not able to track any changes in patients' diets or pharmacotherapy regimen during the 3-month period, it is hard to give an accurate opinion about the nonsignificant change in average HbA1c percentage.

Although HbA1c did not decrease significantly in this study ($8.1\% \pm 0.7\%$ vs. $7.6\% \pm 0.4\%$), a previous study which investigated the short-term impact of HbA1c on morbidity of people with type 2 diabetes during a 6-year period showed that in diabetic people who have initial HbA1c level above 8%, a decrease in this percentage is associated with reduced mortality among these patients.^[28]

Pharmacists can play an important role in the safe and efficient use of insulin pen by elderly diabetic patients through minimizing the likelihood of medication errors associated with inappropriate insulin pen use, including preparation, administration, and storage. The present investigation was subject to some limitations; this study utilized data from a single center and was conducted during a short period on a limited number of patients who visited the outpatient section of the hospital pharmacy. Studied sample may not be a complete representative of the general population of diabetic patients, especially younger patients or those with type 1 diabetes. Furthermore, the given answers by old and mainly low educated patients make the judgment about the reliability of the answers even harder.

Pharmacist-conducted educational interventions had a positive impact on self-administration of insulin pens in

diabetic patients. These interventions led to a significant decrease in the rate of medication errors associated with inappropriate insulin pen use as well as an improvement in glycemic control of the patients. Integration of pharmacists in diabetic management of patients, especially in rural area with limited access to diabetes educators, can be beneficial. Further research is recommended to assess the effectiveness and sustainability of pharmacist-led educational interventions on safe insulin pen use.

Educating older patients and their caregivers on appropriate techniques of insulin pen use have a positive impact on diabetes management and error prevention.

Pharmacists can play an important role in safe and efficient use of insulin pen in elderly diabetic patients by minimizing the likelihood of medication errors associated with insulin pen use.

AUTHORS' CONTRIBUTION

Aida Sefidani Forough contributed to the conception, design, acquisition, analysis and interpretation of data as well as preparing the manuscript. Parsa Riazi Esfahani contributed to data analysis, drafting and revising the manuscript.

Acknowledgments

The authors would like to thank Prof. Fanak Fahimi for her valuable comments on this study. The authors also would like to thank the nursing staff in Amiral Momenin General Hospital, Khodabandeh, Iran, for their help in data collection stage.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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