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Quality of life of insulin dependent diabetic patients who do not have access to insulin pens: a cross-sectional study from Palestine

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ABSTRACT

Diabetic patients' numbers are increasing around the world, this metabolic disease affects patient's quality of life in all domains: physically, socially, psychologically and emotionally. As the disease progresses patients need to use insulin. According to the Palestinian MOH (Ministry of Health) 12% of people in Palestine have diabetes. Twenty percent of type 2 diabetic patients visit the MOH clinics and use insulin also 12% use both insulin and oral drugs to control their blood glucose levels. These patients administer insulin subcutaneously by vial and syringe. The aim of this study was to assess QoL (quality of life) of diabetic patients using insulin, factors affecting it, preference of patients to use insulin pen and their willingness to pay for them. Method: A descriptive study conducted with a sample of 311 diabetic patients that use vial/syringe to administer insulin and attending MOH diabetic clinics in Bethlehem and Hebron. A questionnaire was designed to assess four parts; socio-demographic part, patient's health profile, QoL part and willingness to pay for insulin pens part. QoL was measured using SF-36v2® questionnaire and the willingness to pay part validated using pilot study. Results were analyzed using Quality Metric Health Outcomes™ Scoring Software 4.0 and SPSS software. Results and conclusion: The mean scores of QoL domains ranged from 40.7 to 65.6. Diabetic patients had lower scores than general population in all domains of QoL; physical functioning, role-physical, body pain, general health, vitality, role-emotional, mental health, physical composite summary and mental composite summary, except in social functioning. The majority of participants had lower scores than general population in all QoL domains. The results revealed that gender, age and glycemic control, number of family members, duration of insulin use had no significant impact on QoL. Approximately 77% of participants reported having complications, which had a significant negative effect on their QoL (P-value < 0.001 in all domains). Single patients and patients living in Hebron had a significant positive effect on QoL. Higher level of education, high monthly income and being employed had a positive effect on QoL while longer duration of diabetes had negative effect. Eighty-five percent of participants preferred to use insulin pens if it was available as a choice in the MOH; 35% of them were willing to pay extra money to get insulin pens instead of vial/syringe. This study revealed that the QoL of diabetic patients using insulin in this sample was low, which could be increased if the government included insulin pens in the MOH drug list.

KEYWORDS: Quality of life; Diabetes mellitus; Willingness to pay.

INTRODUCTION

The number of diabetic patients is increasing around the world. It was estimated using 133 studies from 91 countries that the number of diabetic patients will increase from 2010 to 2030 by 54%, the number in developing countries was expected to increase by 69%, while in developed countries by 20% [1].

In the Palestinian West Bank the prevalence of diabetes was 15.3% in 2010 and is expected to increase to 23.4% by 2030 [2]. According to the Palestinian MOH (Ministry of Health) the number of deaths caused by diabetes complications was 869 in 2015, which is estimated to be 19.7 out of 100.000 [3].

With the increase in number of people with diabetes, caring for those patients is considered a global challenge. They make a huge effort and many decisions every day and all day long to reach a non-diabetic metabolism rate, which will affect social, physical and emotional aspects of life. So, the

evaluation of QoL (Quality of Life) in these patients is essential to measure psychosocial well-being, the benefits of new treatments and to identify the dissatisfaction of the existing treatments.

Quality of life was defined by the WHO (World Health Organization) in 1947 as the perception of the individual's position in life, including the person's satisfaction of physical health, psychological health and social relationships [4, 5]. Quality of life defined also as the personal evaluation of how good or bad their life is. It evaluates the satisfaction of person's life in many aspects including psychological, environmental, social and physical. HRQoL (Health related Quality of Life) concerns of health aspects as well as general QoL; it is the patient's perception of the effect of illness or treatments on their QoL, these two concepts, QoL and HRQoL, are used interchangeable [5].

Many studies indicated that QoL was lower in diabetic patients than other population [6]. In Gaza diabetic patients had lower scores than non-diabetics in all QoL domains; physical, psychological, environmental and social relationships [7]. In North West Bank a recent study found that 30% of type 2 diabetic patients had poor general health and moderate pain [8], while within type 1 diabetic patients a recent study showed that the mean score of QoL ranged from 51.7% to 75.6%, the highest scores were in the bodily pain domain and the lowest in general health domain. Those results were lower than QoL of type 1 diabetes in other populations [9]. Diabetic Patients from two clinics, Al-Watani Hospital and Al-Makhfyah primary health care clinic in Nablus were studies it was found that older age being unemployed and the presence of comorbidities were associated with lower QoL. On the other hand treatment satisfaction was not associated with HRQoL [10].

Studies have found that the presence of complications have a negative effect on QoL of diabetic patients [11-13]. Quality of life was also found to be affected by many factors; HbA1c levels, number of insulin injections, type of diabetes, duration of diabetes, monthly income and age [6, 7, 9, 12, 14-17].

In order to achieve glycemic control multiple daily injections of insulin are recommended for patients. Many patients treated with insulin fear the needles, lack sufficient diabetes education and deny the need for insulin, all these reasons contribute to the non-adherence in those patients [18, 19]. Many studies have also found that the QoL of diabetic patients can be improved by the use of insulin pens for insulin delivery [20, 21].

Many studies assessed the preference of patients to use insulin pens over syringe/vial and found that most patients preferred the use of insulin pens when they had used both [13, 22, 23].

The aim of our study was to describe the QoL of diabetic patients that use insulin in the MOH clinics in Bethlehem and Hebron and to identify important variables that affect QoL for these patients. The secondary aim was to assess the preference of diabetic patients for insulin pens and the amount of money they are willing to pay for them.

METHODS

Study population

This was a cross sectional study among diabetic patients that use insulin in Bethlehem and Hebron MOH clinics. The target population for this study was diabetic patients that use insulin by vial/syringe and attend the MOH clinics in Bethlehem and Hebron. Ethical Approval for this study was obtained from Palestinian Ministry of Health (Reference number 1035/56 3/10/2016). Ministry of health facilities have purposely chosen based on the high percentage of diabetic patients attending these health care facilities. Inclusion criteria for patients were: Diabetic patients using insulin by vial/syringe, diagnosed with type 1 or 2 diabetes and being 17 years old and more (both male and female). Exclusion criteria were patients who did not agree to participate; patients use only oral hypoglycemic drugs and patients using insulin pens during the time of the study. 30 patients were recruited to perform a pilot study of the WTP (willingness to pay) domain in order to test if it was appropriate and clear for the patients.

Our sample was 311 patients. All eligible patients were approached as they came in for routine follow-ups during the data collection period in the primary health clinics. Patients who met the study inclusion criteria were asked if they were willing to participate

in the study by completing the questionnaire while they were waiting to see the doctor. Verbal consent was obtained from each patient prior to completing the questionnaire. The interview with participants needed from 15 to 20 minutes.

Questionnaire

In our study, we used a questionnaire of four parts; socio-demographic, health profile, quality of life and willingness to pay. The socio-demographic information sheet covered the following areas of interest: Gender, age, educational level, occupation, marital status, residency and income status. Health profile part included duration of diabetes, duration of insulin use, type of diabetes, HbA1c (glycated hemoglobin) level, type of treatment, incidence of hypoglycemia, insulin dosage regimen and presence of complications.

The Palestinian version of SF-36v2® Health Survey was used to assess quality of life for diabetic patients using insulin. The Non-Commercial License Agreement was obtained from OptumInsight Life Sciences incorporation (OPTUM). SF-36v2 is a valid survey that has been used in many studies. The certificate of Arabic (for Palestine) of the SF-36v2® Health Survey was obtained from the OPTUM incorporation. We used the eight domains measured by SF-36; physical functioning (PF), role physical (RP) which is role limitation due to physical health issues, bodily pain (BP), general health (GH), vitality and energy (VT), social functioning (SF), role emotional (RE) that is role limitation due to emotional problems and mental health (MH) to assess quality of life. Also the two summary components were used that are 1-physical component summary (PCS), which represents physical limitations, disabilities and the presence of fatigue and body pain. 2-The mental component summary (MCS), which evaluates psychological distress and limitations due to emotional problems. The scoring range of the eight scales ranges is from 0 to 100, higher scores indicates a better quality of life.

WTP survey was used in this study to examine the patient's preference for the insulin pens and their willingness to pay for those pens.

Data analysis

The questionnaires were filled and the data for QoL part were introduced in the Quality Metric Health Outcomes™ Scoring Software 4.0. The results were in a scale of 0 to 100. These results from the software were introduced into the SPSS program. A one-way Analysis of Variance (ANOVA) was used to compare differences between subgroups of independent categorical variables. Post-hoc analyses (Scheffé's Post hoc Test) was then conducted to test for differences between the groups to determine if the overall ANOVA was statistically significant. For interpretation of the results, P <0.05 was considered to be statistically significant. Confidence intervals were calculated at the 95% level of confidence. Multiple regression analysis was used to test which variables significantly predicted PCS and MCS.

RESULTS

Socio-economic and health profile

The sample used was 311 patients distributed as 114 patients in Bethlehem and 196 patients in Hebron Socio-economic information summary of the sample is presented in Table 1.

Table (1): distribution of the participants by socio-demographic characteristics.

Variable		Frequency	Percent
Age, years	17-40	78	25.3%
	41-59	120	38.9%
	>60	110	35.7%
Gender	Female	162	52.1%
	Male	149	47.9%
Marital status	Married	264	84.9%
	Widow	21	6.8%
	Single	25	8.0%
	Divorced	1	0.3%
Education level	No schooling	110	35.%
	Elementary and secondary school	160	51.%
	Diploma	15	4.8%
	Professional	26	8.4%
Employment status	Full time-job	47	15.%
	Part time-job	17	5.5%
	No work	246	79.%

Most subjects 269 patients (86.5%) had type 2 diabetes and 42 (13.5%) had type 1. Almost 50% (169) of the subjects reported that they had hypoglycemia in the past four weeks. When patients were asked about their insulin regimen, 210 (67.5%) of participants reported they used insulin two times daily, 71 (22.8%) three times and 30 (9.6%) once daily. The mean level of HbA_{1c} was 9% with a standard deviation of 2. The majority of patients (97%) (254 patients) had HbA_{1c} level of 7 and higher while only 3% (8 patients) had HbA_{1c} level of less than 7.

The duration of diabetes ranged from less than a year to 59 years with a mean of 14.9 years (±SD 13.6). The average duration of using insulin was 6.6 years. Sixty-seven (21.6%) of patients reported they had one complication, 74 (23.8%) reported two complications and 98 (31.4%) reported from 3 to 7 complications. The most frequent complication between patients was visual disorders (58%, 180 patients), followed by neurological disorders (42%, 51 patients), heart disease (31%, 97 patients), stroke (22%, 67 patients), renal complications (16%, 51 patients) and foot ulcers (14%, 42 patients). The least common complication was gangrene. On the other hand, 70 patients (23%) reported they had no complications of diabetes.

QoL scores

The mean scores of the quality of life domains are shown in table 2. The domain with the highest score was social functioning (M = 65.6, ±SD 36.2), followed by physical functioning (M= 58.91, ±SD 31.2) and role emotional (M = 58.91, ±SD 34.58). The lowest was vitality (M = 40.7, ±SD). The mean score for physical component summary was lower than mental component summary. The percentage of patients that had scores above the general population norms appears relatively low for all domains (ranging from 12% to 30%).

Table (2): Mean scores of participants' quality of life domains, standard deviation and percentages of participants whose scores were above or below the general population norm.

Domains	Mean	SD	Above the general population norms* (%)	Below the general population norms (%)
PCS (Physical Component Summary) (PCS)	41.42	11.67	17	63
PF (Physical Functioning)	58.92	31.2	19	56
RP (Role Physical)	44.25	36.72	17	68
BP (Bodily Pain)	49.03	32.64	21	60
GH (General Health)	48.3	22.0	12	58
MCS (Mental Component Summary)	41.32	12.19	15	59
VT (Vitality)	40.73	27.01	18	59
SF (Social Functioning)	65.61	36.23	43	45
RE (Role Emotional)	58.91	34.59	30	60
MH (Mental Health)	54.25	24.33	16	62

* U.S general population norms.

Factors affecting QoL

There was no significant relationship between gender and QoL domains except for body pain in which men had a higher score than women. Age also didn't affect QoL domains. The mean score of all domains was higher for patients in Bethlehem relative to Hebron (3 points difference in MCS and PCS between patients in Bethlehem and Hebron, p-value < 0.05). Single patients had higher scores in all domains compared to married and widow (13 points difference in PCS, p-value < 0.001). Participants who were illiterate had lower mean scores in all domains than those who had primary or secondary education, diploma and university level of education (12 points difference in PCS and 7 points in MCS between patients that are illiterate and who have a university degree, p-value < 0.05). There was a significant positive relationship between working and QoL

(8 points difference in PCS between patients that have a full-time job and who are unemployed, p-value 0.000). On the other hand, there was no significant relationship between the place of living; village, city or camp and QoL domains, QOL was not also affected by the number of family members. Participants with higher income had a higher mean QoL scores (14-20 points difference in PF, SF and RE, $p< 0.05$).

The mean scores for PF, RP, BP and PCS QoL domains were lower in patients who had been diagnosed with diabetes for longer duration. The differences between patients had diabetes for less than 6 years and who had it for more than 10 years were: 16 points in PF, 16 points in RP, 11 points in BP and 7 points in PCS (p-value < 0.05), the worst values were reached after 10 years. The duration of using insulin didn't affect QoL scores. The mean scores for all QoL domains except MH, MCS and RE, were significantly higher for type 2 diabetes patients than type 1 (p-value < 0.05). There was no significant relationship between QoL and HbA_{1c} levels. The only domain that was significantly affected by the insulin regimen was GH with a 5 points difference between once and three times regimen. The mean scores for all QoL domains were significantly higher for patients with lower number of complications (15 points in PCS and 13 points in MCS difference between patients had no complications and who had more than 4 complications, p-value<0.001).

Multiple regression analysis was used to test which variables significantly predicted PCS. The results indicated that the type of diabetes, duration of diabetes, level of education and employment were significant predictors of PCS (p-value < 0.05). These four predictors explained 26.9% of the variance in PCS; type of diabetes caused 14.2% of the variance followed by duration of diabetes (5.8%), level of education (4.7%) and employment (2.2%). On the other hand, MCS was significantly predicted by level of education.

Willingness to Pay

181 of subjects (58.2%) reported that if both choices pens and syringes were available they will choose pens and 130 (41.8%) will choose syringes. 130 (41.8%) of participants didn't answer the question if they are willing to pay more for the pens, 110 (35.4%) reported they will and 71 (23%) reported that they will not pay more.

As shown in table 3, the most common two reasons reported by participants for choosing pens were that they are easier to use and inject than syringes. On the other hand, the majority of patients 166 (92%), who chose vial/syringe reported that they chose vials because they are used to them.

Table (3): Reasons reported by patients for choosing pens and syringes.

	Reasons Easier to use	**% of patients 92%**
What was important to you when you chose pens?	Easier to inject	87%
	More accurate in measuring the dose.	66%
	Need less time for the injection	70%
	Causes less pain	65%
	More lifestyle and social life flexibility	82%
	Reading the dose is easier	79%
What was important to you when you chose vial/syringe	used to it	92%
	Less cost	72%
	Hard to learn to use pens	34%
	Easy to use vials	81%
	Easy to inject by syringe	73%
	Feel more confident about the dose accuracy	64%
	Less painful	34%
	Syringes don't interfere with daily activities	69%
	Easy to read the dose	77%
	Believe to be more able to control blood sugar	77%

DISCUSSION

The results of this study agrees with a previous study assessed QoL of type 2 diabetics in North West Bank [8]. They are also consistent with other studies examined QoL in diabetic patients and found that diabetes mellitus affected health-related quality of life of the participants [6, 24]. When compared to a study in New Delhi, all domains except general health were lower in our study [25]. Also, compared to a recent study in Saudi Arabia, the scores of QoL were lower in all domains except social functioning compared to the Saudi patients' scores [26].

We found no significant relationship between glucose control (HbA_1c levels) and QoL, which was consistent with most studies that found no relationship between glucose control and QoL [27, 28]. Complications had a very clear negative significant effect on all QoL domains, many other studies showed a negative impact of complications on QoL [7, 12, 13]. This study found that the mean scores of QoL domains were higher for type 2 than type 1 diabetes, which is consistent with other studies [15], The differences between the two types could be due to the differences in age and treatment regimens **[28]**. In all QoL domains, patients with a monthly income more than $880 scored better than patients with income less than $880 this was consistent with a study that found that diabetic patients who had more than $530 monthly income had better QoL than who have no regular income [7]. There was no significant relationship between gender and QoL except in BP domain, this result is consistent with other studies that assessed the QoL of diabetic patients in Gaza [7]. In this study, it was found that better education was linked to better QoL in all domains, which agreed with another study assessed QoL of diabetic patients using SF-20 [6]. Being employed was also associated with better QoL in all domains, this result agrees with the findings of Eljedi et.al [7] in Gaza and with other studies [14]. These results could be due to the possibility that educated people have better self-esteem, better opportunity for employment, higher income and better social life.

Fifty eight percent of patients preferred insulin pens over syringes to administer insulin, these results are consistent with previous studies that assessed the preference of patients for insulin pens and more than 70% of patients preferred to use pens [22, 23]. Patients were not willing to make a substantial out-of-pocket payment might be because diabetic patients registered in the MOH clinics are used to pay only a co-payment out of pocket for the prescription each month.

Several limitations of this study should be considered when these results are interpreted. The sample is collected from Hebron and Bethlehem so the results cannot be generalized to the Palestinian population. The patients are studied once, and the effect of using insulin pens is not studied. There is no controlled group of patients using insulin pens.

CONCLUSIONS

The majority of participants had lower QoL than the general population norms and the scores of all domains except the physical and social functioning were below 50, which indicated a low QoL. QoL of Diabetic patients using insulin was influenced by residency, marital status, level of education, employment, monthly income, diabetes duration, diabetes type, diabetes complications and insulin regimen. Most patients (58%) preferred to use pens if it was available as a choice for insulin administration. The number of diabetic patients in Palestine is increasing. One of the main objectives of diabetes treatment program is to promote the QoL of diabetic patients. A close look at the health care system is needed in order to try to improve QoL by possible introduction of insulin pens as a choice for diabetic patients using insulin. The introduction of insulin pens will make insulin self-administration easier and will decrease the discomfort of injection, which could increase the QoL, compliance and diabetes complications in the future and eventually reduce the overall health care costs.

COMPETING INTERESTS

The author(s) declare that they have no competing interests.

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