Evaluation of Diabetic Quality of Life Among Insulin Requiring Patients Shifted to Injection by Insulin Pen.

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Abstract

To evaluate the diabetic quality of life (QOL), satisfaction and acceptance of insulin injection by insulin pen device, fifty insulin-treated diabetics (28 IDD and NIDD; age 42.1 + 5.6 years; range 30-50) satisfactorily controlled on two injections of mixed insulin (HbA_{1c} < 9%) are randomized into two groups. Group "A" (n = 32; 16M:16F) was shifted to the same dose of premixed insulin injection by insulin pen, while group "B" (n = 18; 9M:9F) served as a control group, continuing insulin injection by conventional syringe and needle. Over 3 months study period, two sets of questionnaires-proved to have good test re-test reliability were used to evaluate patient satisfaction and QOL. Metabolic control was assessed by measuring the levels of HBA_{1c}.

Insulin pen improved the QOL, where a significant difference was reported in the pen treated group after the 3 months trial period (23.35 ± 9.1 vs. 11.65 ± 3.7; $p<0.01$) as well as on comparing this group versus the control group (18.61 ± 6.4 vs. 11.65 ± 3.7; $p<0.05$). The results show that insulin pen proved to be more convenient, reliable with minimal mechanical problems, giving accurate dose, adding a difference to the patient's life and that most of the patients are feeling less conspicuous carrying the insulin pen. Although there was no significant difference in glycaemic control after the usage of the pen injection device (HbA_{1c} 7.5 ± 1.1 vs. 7.4 ± 1.0), the insulin pen, in the scope of its betterment of the diabtic QOL, is highly recommended for young, motivated insulin treated diabetics with less than 36 unit per injection.

Introduction Insulin pen (dial a dose cartridge injector) was developed so as to deliver short-acting intermediate and pre-mixed insulin in accurate dosing to such diabetics requiring less than 36 unit of insulin per injection as an alternate to conventional syringe and needle. The pen was originally invented to facilitate and simplify the injection of soluble insulin to the IDD patients on intensified regimen of soluble insulin therapy.

The development of such injection devices has not only facilitated multiple daily insulin injections but has also greatly increased acceptance of this type of insulin strategy. As a result, the advantages of insulin injection by insulin pen can be also utilized by NIDD patients.

Difficulties arise when therapy is increased from 1 to 2 or more injections per day. In addition, errors in filling and reading syringes have to be considered in patients with visual impairment and in elderly diabetics with poor manual dexterity (*Zeumzem et al., 1988*).

In a study on insulin pen and intermediate acting insulin penfill, the investigators reported that several patients stated that injections were less painful than syringe and needle, although the outer diameter and length of the needle were identical. Most of the patients studied reported as well a feeling of well-being while on pen treatment suggesting that insulin penfill system relieves some of the burdens of the daily life for insulin dependent diabetics (*Kolendorf et al., 1988*).

Trials of using the insulin pen for delivery of pre-mixed insulin revealed that it improved the compliance of the patients to the treatment, achieving the same glycaemic control as that of insulin mix at ratio ranging from 20:80 to

40:60 and being more convenient for the patients and with no difference in the incidence of hypoglycaemia (*Chester et al., 1988 and Coscelli et al., 1990*).

It is well known that psychological and emotional factors affect glycaemic control in diabetic patients (*Shilittoe, 1989*). So, confidence about their diabetic control, the treatment given and the changes in patient's perception of the effect of being diabetic on their lives are to be considered carefully in the comprehensive diabetic management.

Two recent studies concerning treatment of diabetes and QOL while using insulin pen are extremely contradicting, while the first study carried out in Oslo, revealed that shift to insulin injection by pen proved to be more practical and easy to use, gave more freedom made social life easier and improved blood glucose control (*Andresen et al., 1989*), the second study, carried out in London, revealed that a change to pen will not necessarily lead to a significant improvement in the patient's QOL, nor will it be more acceptable to all patients than a conventional syringe and needle (*Henderson & Tindall, 1990*).

Although the latter study innovated an excellent set of questionnaires to evaluate diabetic QOL and consumer satisfaction that could be a standard way of such evaluation - three objections have to be considered before accepting its results as indubitable: the first is that it was carried out on a small number of patients, the second is that it was carried out on poorly controlled, less motivated group of patients and lastly the mean age of the group studied was relatively high. All these factors could lead to a less rectified appraisal of the actual value of the insulin pen.

Reconsidering such trial on a large number of younger-aged and satisfactory controlled diabetics, while fixing the same scales of evaluations, could invalidate these conclusions.

Patients and Methods Fifty insulin - treated diabetics (28 IDD and 22 NIDD with failure on dietary and orally hypoglycaemic drugs) participated in this study. All of them were treated by 2 injections of mixed insulin per day, each injection being less than 36 unit of insulin. Each patient is well controlled on that regimen with $HbA_{1c} < 9\%$. The included patients were randomized in two groups:

Group A: Comprised 32 diabetics (age 42.3 ± 5.7 years; 16M: 16F), who were shifted to the same dose of premixed penfill insulin (Actraphan HM TM) injection by insulin pen (Novopen II).

Group B: Comprised 18 diabetics (age 41.5 ± 5.5 years; 9M: 9F), who served as a control group, continued receiving insulin by the conventional syringe and needle method.

Over three months (study period) the 2 groups were asked monthly to answer QOL questionnaire (Table 1). The control group answered the same questionnaire once more after 2 weeks to calculate the test re-test reliability of the QOL questionnaire.

Nine other questions were asked monthly to each patient in group A to evaluate his satisfaction about insulin injection by pen (Table 2).

HbA_{1c} was measured every 6 weeks together with the mean daily plasma glucose to evaluate the glycaemic control over the trial period. Table (3) summarises the baseline data of each group.

Statistical methods The total score of the QOL response is 80, where 0 score = no effect on the QOL while 80 score = maximal alteration in the QOL. Data are calculated as the mean of the norms ± standard deviation (SD). Responses to the patient's satisfaction questionnaire were calculated as the percentage of the response (%). Comparisons between the control group versus the insulin pen group was done using t-test for odd data, while comparisons with the insulin pen group over the time period was calculated by t-test for even data. Data are collected, calculated and the

graphs were made using Excel 4.0 computer program (Microsoft Company).

Results Test re-test reliability of QOL questionnaires shows positive correlation for the 8 items included (r = 0.86).

The results of the patient satisfaction questionnaires were in favour of insulin pen over the conventional syringe and needle (Figure 1).

On repeating the questions monthly to the same group of patients, it was noted that with passage of time a higher percentage of patients became more satisfied with the pen (Figure 2).

Considering the QOL questionnaires, significant differences were reported in the insulin pen group over the three-month period (23.35± 9.1 vs. 11.65 ± 3.7; P<0.01), as well as on comparing the control group versus the insulin pen group by the end of the trial (18.61 ± 6.4 vs. 11.65 ± 3.7; P < 0.05) (Figure 3).

No significant change in the glycaemic control was noticed in the groups studied, where a non-significant change in the HbA_{1c} was noted after the 3-month period either in the insulin pen group (7.5 ± 1.1% vs. 7.4 ± 1%, P>0.05) or in the control group (7.3 ± 1.3% vs. 7.2 ± 1.2%, p>0.05). Also a non-significant change was reported in the mean daily plasma glucose (8.5 ± 2.3 mmol 1/1 at abseline vs. 8.2 ± 2.1 mmol 1/1 after usage of the pen, p>0.05) (Figure 4).

No clinical difference in the number or severity of hypoglycaemic attacks was observed.

Discussion Introduction of such a device renders multiple daily insulin injection more acceptable to diabetic patients and was appreciated by most diabetologists. Such a considerable progress in insulin delivery systems has a lot of advantages, as it delivers properly an accurate dose, appearing simple and very easy to use and being easily carried and manipulated, providing a sufficient education to the patient is offered on its usage prior to allowing him to use it. Unfortunately, younger, socially active frequently travelling diabetics as well as patients with tight daily schedule need no longer carry syringes, ampoules....etc, and that sense of freedom improves their psychological state.

From another point of view, there are important psychological reasons for choosing pen insulin therapy, as in contrast to a syringe, which carried the image of the disease and is a symbol of pain. An insulin pen does not evoke thoughts of the disease, but instead, it appears to be a positive symbol which might foster a positive attitude towards therapy in diabetic subjects (*Marrain, 1989*). Lastly, it could be considered more economical on the long run.

So, unsurprisingly we found a great acceptance of the group studied to insulin pen, as they are relatively younger. And again, well controlled diabetics are more motivated and consider such device a real addition to their active attempt for controlling their hyperglycaemia. Because more than 2 injections is much suitable for younger IDD, no improvement in the glycaemic state was noticed in the group studied, but as regular insulin is also available in cartridge ready for use by insulin pen, more than 2 injections of soluble insulin could be more suitable for highly motivated younger IDD.

QOL is defined as the extent to which being diabetic and taking insulin affects the patients' lives and their confidence that they have good control over their symptoms (*Henderson & Tindall, 1990*). Questionnaires could actually reflect the exact psychological reaction of the patients to their disease and therapy, provided that these questions have to be applied to a large group of patients before being considered as statistically significant. That is why significant improvement in the QOL was noticed in that group studied. Recent trials using different questionnaires are also supporting such improvement in the QOL among diabetics shifted to insulin pen (*Andresen et al., 1989 and Tublana - Rufi et al., 1989*).

Diabetics in the Middle East, as well as all other patients in similar developing counteries, are known to have poor compliance to drug therapy and so positive results in this case have a double value in recommending such

method not only in the Middle East area but also for communities with known good compliance and with above average medical background knowledge.

In conclusion, insulin pen improved the QOL and is well accepted by young motivated diabetics requiring less than 36 units of premixed insulin per injection.

Table 1: The diabetic quality of life (QOL) questionnaire

Please for each question circle a number between one and 10 that best represents your feeling and impression.

* **How much does being diabetic interfere with your day to day life?**

NOT AT ALL — **A GREAT DEAL**

1 2 3 4 5 6 7 8 9 10

* **How much does being diabetic interfere with your social life?**

NOT AT ALL — **A GREAT DEAL**

1 2 3 4 5 6 7 8 9 10

* **How much does taking insulin interfere with your daily routine?**

NOT AT ALL — **A GREAT DEAL**

1 2 3 4 5 6 7 8 9 10

* **How much does taking insulin interfere with your social life?**

NOT AT ALL — **A GREAT DEAL**

1 2 3 4 5 6 7 8 9 10

* **How easy is it to give yourself insulin?**

VERY EASY — **EXTREMELY DIFFICULT**

1 2 3 4 5 6 7 8 9 10

* **How convenient is the system you use for insulin administration?**

VERY EASY — **EXTREMELY DIFFICULT**

1 2 3 4 5 6 7 8 9 10

* **How painful/uncomfortable is injecting yourself with insulin?**

NOT AT ALL — **EXTREMELY SO**

1 2 3 4 5 6 7 8 9 10

* **Do you feel self-conscious about injecting yourself?**

NOT AT ALL — **EXTREMELY SO**

1 2 3 4 5 6 7 8 9 10

Table 2: The patient satisfaction questionnaire

Please answer by YES or NO.	
Q1.	Has the insulin pen made a difference to your life?
Q2.	Did you find it easy to use?
Q3.	Was it more convenient than your old method of injecting insulin?
Q4.	Did you find it reliable?
Q5.	Did you trust it to give you the correct dose?
Q6.	Did you feel less conspicuous carrying the insulin pen?
Q7.	Did you have any mechanical problems with the insulin pen?
Q8.	Would you recommend it to other diabetics?
Q9.	Will you be keeping the insulin pen?

Table 3: Baseline data of the groups studied

	Insulin pen group	**Control group**
Total number	32	18
IDD	19	9
NIDD	13	9
Male	16	9
Female	16	9
Age	42.3 ± 5.7	41.5 ± 5.5
Total number	8.5 ± 2.3	8.4 ± 2.1
IDD	7.5 ± 1.1	7.3 ± 1.3

Figure 1: Response to the patient satisfaction questionaires after 3 months of insulin pen usage

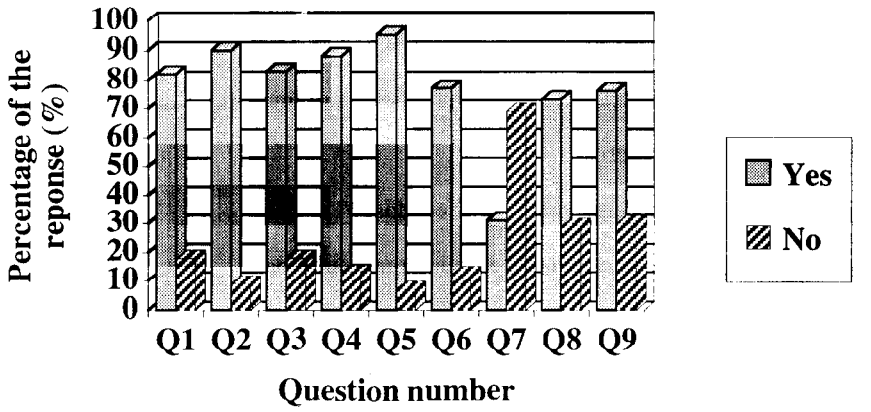


Figure 2: Response to the patient satisfaction questionaires over 3-month period of insulin pen usage

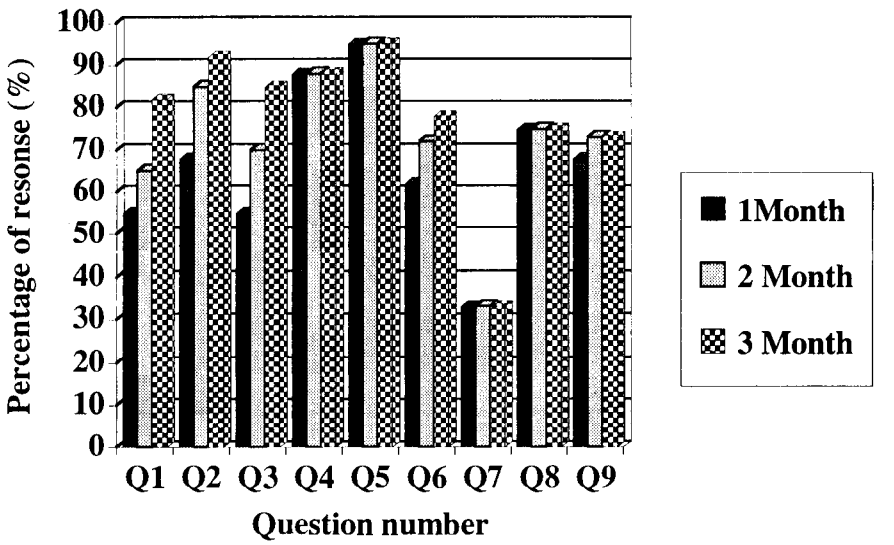
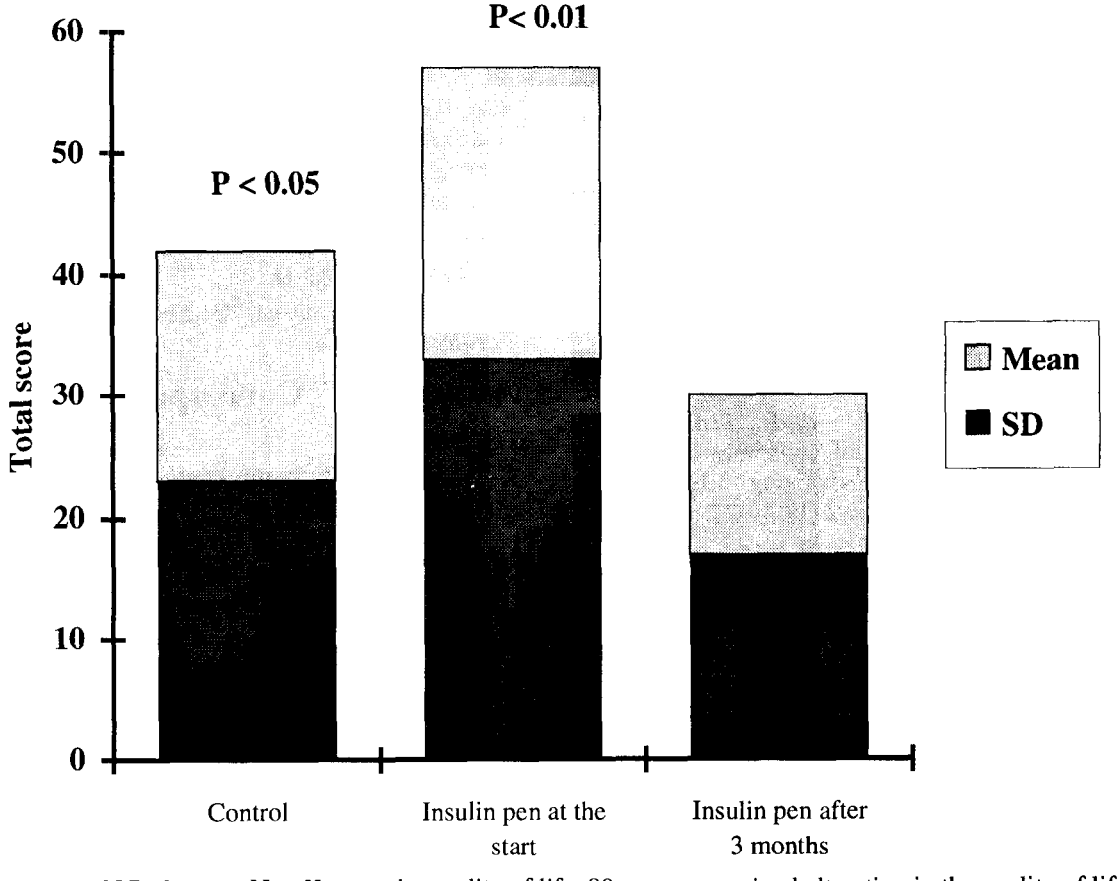


Figure 3: Comparison between the total score of response among the insulin pen group after 3 months versus the same group at the start and versus the control group



N.B. 0 score: No effect on the quality of life, 80 score = maximal alteration in the quality of life

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تقويم طبيعة أو "نوعية" الحياة لدى مرضى السكر المحتاجين للأنسولين والذين تحولوا إلى إستعمال جهاز "قلم الأنسولين"

لتقويم نوعية الحياة لدى مرضى السكر من حيث الرضا والتقبل لحقن الأنسولين بواسطة "قلم الأنسولين"، تم إختيار عينة من خمسين مريضا تحت العلاج بالأنسولين المخلوط متوسط أعمارهم ٤٢,١ ± ٥,٦ ويقعون جميعا مابين سن الثلاثين والخمسين. وقسمت العينة عشوائيا إلى مجموعتين، المجموعة "أ" (٣٢ مريضا نصفهم من الذكور ونصفهم من الإناث)، وتم تحويلها إلى الحقن بنفس الجرعة من الأنسولين المخلوط بواسطة قلم الأنسولين، بينما ظلت المجموعة "ب" (١٨ مريضا) تتناول الأنسولين المخلوط بواسطة الحقن بالطريقة التقليدية (المحقن ذو الابرة).

وخلال فترة زمنية أستمرت ثلاثة شهور طبقت إستبانات فى بدايتها وعند نهايتها لتقويم رضا المرضى ونوعية الحياة، كما تم تقدير التحكم الأيضى من خلال القياس الدقيق لنسبة السكر فى الدم.

وقد وضح أن طريقة الحقن بقلم الأنسولين قد حققت نتائج ذات دلالة إحصائيه لدى المجموعة "أ" خلال مدة الإختبار بالمقارنة مع المجموعة "ب" حيث ثبت أنها توفر مزيدا من الراحة وتحدد الجرعة وتقلل من المشكلات، فضلا عن تحقيق نوعية حياة أفضل بسبب سهولة حمل الجهاز.

ولم تظهر فروق ذات دلالة إحصائية فى التحكم فى نسبة السكر بالدم بين الطريقتين. وبناءا عليه رأت الدراسة نشر هذه الطريقة بين المرضى تحت العلاج بالأنسولين خاصة صغار السن المحتاجين لجرعات أقل من ٣٦ وحدة يوميا بطريقة الحقن.