



Knowledge, Practice, and Complications of Insulin-Self Injection among a Representative Sample of Diabetic Patients in Southern Tunisia

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Authors' contributions

This work was carried out in collaboration among all authors. Authors NK, YM, DBS, FHK, SJ, SY, JD, NR, ME and HC have made substantial contributions to conception and design the study, did acquisition of data, analysis and interpretation of data. Authors NK, YM and DBS wrote and revised the article for important intellectual content. Authors NK, YM, DBS, FM, JJ and MA read and approved the final version of the submitted manuscript. All Authors were involved in drafting the manuscript or revising it critically for important intellectual content. All authors agreed to be accountable for all aspects of the work. All authors read and gave final approval of the version to be published.

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ABSTRACT

Objective: Our study aimed to assess knowledge and practice of Tunisian diabetic patients regarding insulin-self-injecting and to determine insulin-injection complication as well as their independent factors.

Methods: It was a cross sectional study using investigator-administered-questionnaires among insulin self-injecting patients with DM attending Tunisian Endocrinology department on April 2021. Information regarding knowledge and practices relating to injection Technik and its complications were assessed by the insulin Injection-Technique-Questionnaire (ITQ).

Results: A total of 96 diabetic patients were included in the study. The median age was 45 years with IQR=[36-60] years. There were 53(55.2%) subjects with diabetes type 1. Median insulin seniority was 10 years; IQR=[5-20] years. Prevalence of insulin-induced lipodystrophy among patients examined by healthcare worker was 55%. Independent factors of detected lipodystrophy were HBA1C level >10% (AOR=22), family history of diabetes (AOR=0.02), using warmed insulin (AOR=0.08), skin disinfection (AOR=0.005) and skin fold before injection (AOR=0.04). Prevalence of bleeding after injections was 87.5% (n=84). Its independent factors were skipping injections (AOR=27.6), HBA1C level >10% (AOR=10.6), seniority of diabetes >10 years (AOR=41.2) and history of chronic disease (AOR=15.4). Prevalence of pain while injecting was 54.2%. Independent factors of injection pain were having surgical history (AOR=20.2), dyslipidaemia (AOR=19), urban area (AOR=0.021), family history of diabetes (AOR=0.075) and insulin seniority >12 years (AOR=0.086). Leakage or backflow of insulin from skin was reported by 44 patients (45.8%). Its independent factors were dyslipidaemia (AOR=10.7), unmarried patients (AOR=4.7) and obese patients (AOR=0.1).

Conclusion: A poor level of knowledge as well as frequent insulin-injection-complications were observed. Thus, healthcare-providers should pay more attention to therapeutic education on insulin treatment.

Keywords: Complications; diabetes mellitus; insulin; knowledge.

1. INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic diseases characterized by elevated levels of blood glucose resulting from defects in insulin secretion, insulin action, or both [1]. It is a common disorder with increasing prevalence worldwide which makes it one of the major public health problems affecting over 537 million people globally according to the international diabetes federation [2] with an agreed target to halt the rise in DM by 2025 [3]. Inadequate control of blood glucose levels can lead to several disorders which are leading causes of morbidity and mortality especially in developing countries [3–5]. Diabetes self-management behaviours are necessary to ensure optimum glycaemic control [5]. Many diabetics patients eventually require insulin to maintain adequate glycaemic control. Insulin is an effective treatment to manage DM but also depends on the external environment. Insulin self-injection by the pen use vary widely between countries with higher rates of use in Europe (about 80%) and lower rates in the USA (about 15%) [6] in 2008. Recent survey showed that this use raised in USA and in Europe to attend 59% and 93.6%, respectively [7]. Lack of knowledge and irrational practices toward appropriate insulin delivery techniques may end up in therapeutic failure and increase the costs of therapy. Consequently, diabetic patients' adherence to insulin delivery recommendations is critical for better effectiveness [8]. In fact, good adherence to insulin treatment, which is a part of self-management, compared to a low-level of adherence, has been associated with improved

levels of glycaemic control [3] which, in turn, reduces the risk of acute and chronic diabetic complications.

Thus, better management of DM among those on insulin requires determining the level of patient knowledge and adherence to insulin therapy [3]. There was scarcity of data assessing rates of good practice towards insulin self-injection worldwide. High rates of inadequate insulin-injection practice was noted in developing countries [9,10].

In this context, studies that examine diabetes knowledge and adherence are limited in the North African region and especially in Tunisia. Tunisia is a small, middle-income country in the North African region facing an increasing older population [11] with higher prevalence of DM [12]. The present study aimed to assess knowledge and practice on insulin among Tunisian diabetic patients regarding insulin-self administration and to determine insulin injection complication as well as their independent factors.

2. MATERIALS AND METHODS

2.1 Study Design and Settings

It was a cross sectional study using investigator-administered questionnaires among insulin self-injecting patients with DM (type 1 and type 2). The study was conducted at Hedi Chaker Hospital, which is a state-owned public hospital in Sfax, southern Tunisia on April 2021.

2.2 Study Population

All diabetics who had been treated with insulin were eligible for the study. We included all diabetic insulin self-injecting patients who were using insulin as their primary therapy or as additional therapy and attending the Endocrinology department of Hedi Chaker Hospital during April 2021. Participants had to be on insulin treatment for at least 6 months. Patients who were under 16 years of age, who did not consent to participate, or those who were seriously ill, unable to hear or speak, physically disabled, having cognitive impairment and difficulty of getting consent were excluded from the study.

2.3 Sampling Procedures

The source population of our study was represented by diabetic insulin self-injecting patients followed in the Endocrinology department (hospitalization and outpatient department) of Sfax Hospital during April 2021. We opted for an exhaustive sampling.

2.4 Data Collection and Study Tools

The data were collected through a face-to-face interview. A questionnaire was designed to cover four parts and was validated by pre-testing. It collected sociodemographic characteristics, health data and history of chronic diseases, diabetes mellitus characteristics as well as information regarding knowledge and adherence to practices relating to the injection Technik and its complications using the insulin Injection Technique Questionnaire (ITQ) [13].

2.5 Cases Definition

Recommendations of correct injection technique were defined according to the East African Diabetes Study Group (EADSG) Guidelines [14].

Insulin-induced lipodystrophy is defined as a disorder of the adipose tissue. It figures as one of the most common complications of subcutaneous insulin injections and may present as either lipohypertrophy or lipoatrophy [15]. Expert team of healthcare professionals examined patients injection zones to identify lipodystrophy presence.

Bleeding or bruising, injection pain and insulin leakage were involved by direct question to participants.

2.6 Statistical Analysis

Statistical analysis was performed by SPSS. The results of continuous variables were presented as mean \pm standard deviation or median and inter-quartile range (IQR), after verifying the normal distribution. Qualitative statistics had expressed as a percentage at the level of accepted as < 0.05 for significance value. Univariate analysis using the simple logistic regression was performed to assess the odds ratio (OR) of associated factors (OR, 95% Confidence Interval (CI)). Then, all variables significant at $p < 0.2$ in the univariate analysis and those known as associated in literature were entered into a multivariate model using logistic binary regression [adjusted Odds Ratio (AOR); (CI), p] to determine the independent factors associated with different insulin injection complications. P values lower than 0.05 were considered statistically significant.

3. RESULTS

3.1 Patient's Characteristics

As shown in Table 1, a total of 96 diabetic patients were included in the study, among whom 59 cases were females (61.5%), giving a male to female ratio of 0.6. The median age was 45 years with IQR=[36-60] years. There were 38 patients (39.6%) aged over 56 years. We found 39 (40.6%) cases with primary school education levels and 50 (52.08%) cases that had no occupation. There were 54 married patients (56.3%) and 59 cases (61.5%) living in rural areas. A history of chronic disease was noted in 52 cases (54.2%). Among all participants, 37 (38.5%) cases were hypertensive, 23 patients (24%) were dyslipidemic, 15 cases (15.6%) had a history of acute coronary syndrome and 17 patients (17.7%) were obese. There were 15 smokers (15.6%) and 8 alcohol consumers (8.3%) (Table 1).

3.2 Diabetes Characteristics

From the total diabetic patients, 53 (55.2%) subjects had diabetes type 1. The median age of diabetes onset was 32 years with an interquartile range (IQR= [18-42] years). Thirty-eight patients (39.6%) were aged between 56 and 76 years old. The median diabetes seniority was 15.5 years with an IQR = [8-22.75] years. Sixty-nine (71.9%) patients had diabetes for more than 10 years. The mean of haemoglobin A1c (HbA1c) value

was $9\pm 6.1\%$. The mean of fasting blood glucose was 1.97 ± 0.7 g/dl and the mean of postprandial glycemia was 3.2 ± 0.9 g/dl. The haemoglobin A1c (HbA1c) value was above 10% in 45 cases (46.9%). Among all, 87 cases (90.6%) had been hospitalized at least once for diabetes. The most prevalent complication among our diabetic patients was diabetic nephropathy in 42 cases (43.8%), followed by diabetes retinopathy in 36 cases (37.5%) and peripheral diabetic neuropathy in 34 cases (5.4%) (Table 1).

3.3 Insulin Therapy

Main characteristics of insulin therapy: The median insulin seniority was 10 years with an

IQR= [5-20] years. Fifty-four patients (56.3%) were on insulin for a duration less than 12 years. A health education session to support insulin therapy was assessed in 37 patients (38.5%) among whom 24 patients (25%) had a previous session between 5 and 10 years. A training session on insulin injection was performed by a diabetes specialist nurse in 44 cases (44.5%). Overall, 50 patients (52.1%) were on insulin without associated pills. The mean total daily dose of insulin was 40.9 ± 18 units and the number of injections per day was 2.1 ± 0.4 . The basal/bolus insulin regimen was used by 55 patients (57.2%). Eighty-four patients (87.5%) used a syringe for injection. The main injection sites were the abdomen, arms and thighs in 72 patients (75%) (Table 2).

Table 1. Patients' characteristics of the study participants

| Variables | N | Percentage (%) |
|-----------------------------------|----|----------------|
| Gender | | |
| Male | 37 | 38.5 |
| Female | 59 | 61.5 |
| Age categories (years) | | |
| 16-35 | 23 | 24 |
| 36-55 | 35 | 36.5 |
| 56-76 | 38 | 39.6 |
| Profession | | |
| Active | 30 | 31.2 |
| No occupation | 50 | 52.08 |
| Retirement | 16 | 16.66 |
| Marital status | | |
| Married | 54 | 56.3 |
| Unmarried | 42 | 43.7 |
| Education level | | |
| Illiterate | 17 | 17.7 |
| Primary education level | 39 | 40.6 |
| Secondary education level | 35 | 36.5 |
| High education level | 5 | 5.2 |
| Residency area | | |
| Rural | 59 | 61.5 |
| Urban | 37 | 38.5 |
| Socio-economic level | | |
| Low | 54 | 56.3 |
| Mean | 38 | 39.6 |
| High | 4 | 4.2 |
| History of chronic disease | | |
| No | 44 | 45.8 |
| Yes | 52 | 54.2 |
| Family history of diabetes | | |
| No | 61 | 63.5 |
| Yes | 35 | 36.5 |

| Variables | N | Percentage (%) |
|---|----------|-----------------------|
| Corpulence | | |
| Underweight | 2 | 2.1 |
| Normal weight | 53 | 55.2 |
| Overweight | 24 | 25 |
| Obesity class I | 12 | 12.5 |
| Obesity class II | 5 | 5.2 |
| Co-morbidities | | |
| Hypertension | 37 | 38.5 |
| Dyslipidemia | 23 | 24 |
| Acute coronary syndrome | 15 | 15.6 |
| dysthyroidism | 14 | 14.6 |
| History of surgery | 21 | 21.9 |
| Lifestyle behaviors | | |
| Tobacco use | 15 | 15.6 |
| Alcohol consumption | 8 | 8.3 |
| Type of diabetes | | |
| Type 1 | 53 | 55.2 |
| Type 2 | 43 | 44.8 |
| Seniority of diabetes | | |
| < 10 years | 27 | 28.1 |
| > 10 years | 69 | 71.9 |
| Type of insuline as treatment | | |
| Basal/bolus insulin regimen | 58 | 60.4 |
| Basal insulin | 38 | 39.6 |
| Education on insulin injection | | |
| By a nurse working in an endocrinology department | 44 | 45.8 |
| By a nurse working in another department | 23 | 24 |
| By a general practitioner | 2 | 2.1 |
| By a diabetologist doctor | 16 | 16.7 |
| By a medical laboratory professional | 2 | 2.1 |
| By a family member or a friend | 9 | 9.4 |
| History of hospitalisation for diabetes | | |
| No | 9 | 9.3 |
| Yes | 87 | 90.6 |
| Haemoglobin A1c level (N=90) | | |
| <7 | 7 | 7.8 |
| 8-9 | 38 | 42.2 |
| 10-12 | 35 | 38.9 |
| >12 | 10 | 11.1 |
| Complications of diabetes | | |
| Acute coronary syndrome | | |
| Stroke | 1 | 1 |
| Peripheral Diabetic Neuropathy | 34 | 35.4 |
| Diabetic retinopathy | 36 | 37.5 |
| Diabetic nephropathy | 42 | 43.8 |
| Microalbuminuria | 19 | 19.8 |
| Renal failure* | 23 | 24 |
| Diabetic foot | 8 | 8.3 |
| Lower lumb amputation | 1 | 1 |

*: renal failure is defined by a clearance of creatinine < 30

N : Number

Table 2. Insulin therapy characteristics

| Variables | Number | Percentage (%) |
|--|---------------|-----------------------|
| Insuline seniority | | |
| Less than 12 years | 54 | 56.3 |
| Between 13 and 24 years | 32 | 33.3 |
| Between 25 and 36 years | 10 | 10.4 |
| Health education to support insulin therapy | | |
| Not receiving health education | 59 | 61.5 |
| Recent education in the last 6 months | 5 | 5.1 |
| Previous education between 6 months and 1 year | 5 | 5.1 |
| Previous education between 1 year and 5 years | 3 | 3.1 |
| Previous education between 5 years and 10 years | 24 | 25 |
| Training session on insulin injection | | |
| By diabetes specialist nurse | 44 | 45.8 |
| By generalist nurse | 23 | 24 |
| By diabetes specialist doctor | 16 | 16.7 |
| By generalist doctor | 2 | 2.1 |
| By family members or friends | 11 | 11.5 |
| Insulin use | | |
| Without associated pills | 50 | 52.1 |
| With associated pills | 46 | 47.9 |
| Prescribed insulin formulation | | |
| Basal-bolus regimen | 55 | 57.2 |
| Basl-plus regimen | 3 | 3.1 |
| Basal insulin regimen | 38 | 39.6 |
| Number of injections per day | | |
| 1 | 6 | 6.3 |
| 2 | 74 | 77.1 |
| 3 | 16 | 16.7 |
| Devices used | | |
| Syringe | 84 | 87.5 |
| Insulin pen | 12 | 12.5 |
| Injection sites | | |
| Abdomen, upper arms and thighs | 72 | 75 |
| Abdomen and thighs | 5 | 5.2 |
| Abdomen and upper arms | 4 | 4.2 |
| Thighs and upper arms | 5 | 5.2 |
| Abdomen | 5 | 5.2 |
| Thighs | 3 | 3.1 |
| Upper arms | 2 | 2.1 |

Insulin injection practices: knowledge of patients and nurse audit: Overall, 6 patients (6.3%) did change the needle length. According to the rotation of site injection, 84 patients (87.5%) claimed to rotate injections of whom, 54 cases (56.2%) described correctly the rotation and 35 cases (36.5%) were found by nurses to be rotating correctly, 86 patients did change the location of injection at the same site (89.5%). For disinfection, alcohol disinfection of insulin syringe was untamed in 45 cases (46.9%) and alcohol skin disinfection in 80 cases (83.3%). After needle insertion, 59 patients (61.5%) kept it under the skin for less than 5 seconds. The

reuse of needles was found in all patients using insulin pens (N=12) because of economic issues, among whom 8 patients (66%) reuse it more than 10 times. For patients using syringes, reusing disposable needles was found in 66 patients (76.7%), among whom, 54 cases (81.8%) reuse it only 2 times. The main cause of reusing disposable needle was economic issues in 38 patients (42.8%). For insulin storage, 93 patients (96.1%) stored insulin in a refrigerator between 2 and 8 °C before the first use and 89 patients (92.7%) stored it in refrigerator after first use. Twenty-two patients (23%) respected condition of warmed insulin to room temperature

before injection. Of all patients, 45 cases (47%) did not verify the expiration date of insulin and 4 cases (4.2%) did use an expired product of insulin. Only 3 patients (3.1%) used a suitable container to waste needles. Patients were asked to inject insulin behind an expert nurse, a skin fold was realized in 74 injectors (77.1%), among whom 63 patients (85.1%) realized it correctly while 38 (51.3%) patients relaxed skin after removing the needle. Needle entry at an angle of 45 degree was respected by 33 patients (34.2%). Skipping insulin injection was assessed in 69 patients (72%) among whom 22 patients (31.8%) skipped their injection more than 5 times a week.

Insulin injection complications and their associated factors: Ninety patients (93.8%) had at least one complication of insulin injection.

Associated factors of different insulin injections according to the univariate analyses were summarized in Table 3.

1. Insulin-induced lipodystrophy

A systematic examination of insulin injection sites in each consultation by the physician was declared by 23 patients (24%).

-patient report: Of all patients, 45 patients (47%) noticed the presence of lipodystrophy. It was localised in the abdomen in 15 cases (15.6%) and the thigh in 10 cases (10.4%). Among these 45 patients, 3 patients (6%) injected systematically in lipodystrophy zones because they felt less painful.

-examination by a healthcare professional: We examined 60 patients. The prevalence of insulin-induced lipodystrophy among them was 55% (N=33). Most lipodystrophy was noted in the abdominal area in 69.9% (N=23). A mean lesion diameter of 17 ± 4 mm was assessed for abdominal lipodystrophy, 15 ± 5 mm for thigh lipodystrophy and 10 ± 5 mm for upper arm lipodystrophy.

-Independent factors of insulin-induced lipodystrophy detected by expert: Independent factors of detected lipodystrophy were HBA1C level > 10% (AOR=22; CI= [1.5-30]), family history of diabetes (AOR=0.02; CI=[0.002-0.3]), using warmed insulin (AOR=0.08; CI= [0.009-0.7]), skin disinfection (AOR=0.005; CI=[0.001-0.2]) and skin fold before injection (AOR=0.04; CI= [0.003-0.6]) (Table 4).

2. Bleeding or bruising

Overall, 84 injectors (87.5%) claimed to have bleeding or bruising after injections. Of these, 38 injectors (45.2%) had this complication several times a month.

Independent factors of bleeding or bruising were skipping injections (AOR=27.6; CI=[2-38.9], HBA1C level > 10% (AOR=10.6; CI=[1.4-79]), seniority of diabetes > 10 years (AOR=41.2; CI=[3-56]) and history of chronic disease (AOR=15.4; CI=[1.3-17.6]) (Table 4).

3. Injection-pain

Among all patients, 52 injectors (54.2%) reported having pain while injecting. Of whom, 11 (21.1%) patients reported that injections were always painful.

Independent factors of injection pain were having surgical history (AOR=20.2, CI=[1.6-162]), dyslipidaemia (AOR=19; CI=[2-187]). Besides, urban area (AOR=0.021; CI=[0.001-0.4]), family history of diabetes (AOR=0.075; CI=[0.008-0.67]) and insulin seniority > 12 years (AOR=0.086; CI=[0.01-0.7]) were independent factors associated with lower prevalence of injection pain (Table 4).

4. Insulin leakage

There were 44 patients (45.8%) who reported leakage or backflow of insulin from the skin. Of these, 17 patients (38.6%) had insulin leakage several times a month.

Independent factors of insulin leakage were dyslipidaemia (AOR=10.7; CI= [2.2-32]), unmarried patients (AOR=4.7; CI=[1.2-19]) and obese patients (AOR=0.1; CI=[0.02-0.6]) (Table 4).

4. DISCUSSION

To the best of our knowledge, this was the first study involving knowledge and practice of diabetic patients regarding insulin self-administration, insulin injection complications and their associated factors in North Africa. The idea of this study was original and valuable, because studying the practice of insulin self-injection and its associated complications as well as their interfering factors is important for planning therapeutic education among diabetic patients in order to decrease short-term and long-term diabetes-related complications.

Table 3. Associated factors of insulin injection complications

| Variables | Insulin-induced lipodystrophy Total=60 | | | Bleeding/bruising Total=96 | | | Injection-pain Total=96 | | | Insulin leakage Total=96 | | |
|------------------------------------|---|---------------|------------------|-------------------------------|---------------|-------------|----------------------------|---------------|------------------|-----------------------------|----------------|--------------|
| | N (%) | OR [IC] | p | N (%) | OR [IC] | p | N (%) | OR [IC] | p | N (%) | OR [IC] | p |
| Gender | | | | | | | | | | | | |
| Male | 13 (50) | 1.4[0.5-4] | 0.49 | 32(86.5) | 1.1[0.3-3.9] | 0.8 | 17(45.9) | 1.7[0.7-3.9] | 0.2 | 14(37.8) | 1.7[0.7-3.9] | 0.2 |
| Female | 20 (58.8) | | | 52(88.1) | | | 35(59.3) | | | 30(50.8) | | |
| Age categories (years) | | | | | | | | | | | | |
| <35 | 5 (26.3) | 6[1.8-20] | 0.002 | 20 (87) | 1.06[0.2-4.3] | 0.9 | 14 (60.9) | 0.7[0.2-1.8] | 0.4 | 15 (65.2) | 0.35 [0.1-0.9] | 0.03 |
| >35 | 14(73.7) | | | 64 (87) | | | 38 (52.1) | | | 29 (39.7) | | |
| Marital status | | | | | | | | | | | | |
| Married | 21(67.7) | 0.3[0.1-0.9] | 0.04 | 48(89) | 0.7[0.2-2.5] | 0.6 | 25(46.3) | 2[1.2-4.7] | 0.07 | 19(35.2) | 2.7[1.1-6.2] | 0.018 |
| Unmarried | 12 (41.4) | | | 36(85.7) | | | 27(64.3) | | | 25 (59.5) | | |
| Education level | | | | | | | | | | | | |
| Illiterate/Primary education level | 23(67.6) | 0.3[0.1-0.8] | 0.024 | 50(89.3) | 0.6[0.2-2.2] | 0.5 | 27(48.2) | 1.8[0.7-4] | 0.1 | 19 (34) | 3.2[1.4-7.5] | 0.006 |
| Secondary/High education level | 10 (38.5) | | | 34(85) | | | 25(62.5) | | | 25(62.5) | | |
| Profession | | | | | | | | | | | | |
| Active | 9(45) | 0.5[0.18-1.6] | 0.2 | 59(89.4) | 0.6[0.1-2.04] | 0.4 | 35 (53) | 1.1 [0.4-2.7] | 0.7 | 27 (41) | 1.9 [0.7-4.5] | 0.1 |
| Not active | 24(60) | | | 25(83.3) | | | 17 (56.7) | | | 17(56.7) | | |
| Residency area | | | | | | | | | | | | |
| Rural | 20(54.1) | 1.1[0.3-3] | 0.8 | 54(91.5) | 0.4[0.1-1.4] | 0.1 | 37(62.7) | 0.4[0.17-0.9] | 0.034 | 27(45.8) | 1[0.4-2.2] | 0.9 |
| Urban | 13 (56.5) | | | 30(81) | | | 15(40.5) | | | 17(46) | | |
| Socio-economic level | | | | | | | | | | | | |
| Low | 21(61.8) | 1.8[0.6-5.3] | 0.2 | 46(85.2) | 0.6[0.1-2.1] | 0.4 | 29 (53.7) | 0.9[0.4-2.1] | 0.9 | 23(42.6) | 0.7[0.3-1.6] | 0.4 |
| Mean /high | 12(46.2) | | | 38(90.5) | | | 23 (54.8) | | | 21(50) | | |
| History of chronic disease | | | | | | | | | | | | |
| No | 17(54.8) | 1.1[0.3-2.8] | 0.9 | 35(79.5) | 4.2 [1.1-16] | 0.03 | 24(54.5) | 0.9[0.4-2.1] | 0.9 | 21(47.7) | 0.8 [0.3-1.9] | 0.7 |
| Yes | 16(55.2) | | | 49(94.2) | | | 28(53.8) | | | 23(44.2) | | |
| Corpulence | | | | | | | | | | | | |
| Obese | 8(100) | 1.3[1.1-1.6] | 0.006 | 17(100) | 0.8[0.7-0.9] | 0.08 | 15(88) | 8.5[1.8-39] | 0.02 | 4(23.5) | 0.3 [0.1-0.9] | 0.03 |
| Not obese | 25(48.1) | | | 67(84.8) | | | 37(46.8) | | | 40(50.6) | | |
| Hypertension | | | | | | | | | | | | |
| No | 5(71.4) | 0.4[0.06-2.5] | 0.3 | 14(93.3) | 1.2[0.1-14.9] | 0.8 | 8(53.3) | 1.03[0.3-3.4] | 0.9 | 7(46.7) | 0.8[0.2-2.9] | 0.8 |
| Yes | 11(50) | | | 35(94.6) | | | 20(54.1) | | | 16(43.2) | | |
| Dyslipidemia | | | | | | | | | | | | |
| No | 3 (21.4) | 23[3.3-169] | <0.001 | 26(89.7) | 0.8[0.7-1] | 0.1 | 9(31) | 10[2.7-40] | <0.001 | 9(31) | 3.4[1.1-10] | 0.03 |
| Yes | 13 (87.6) | | | 23(100) | | | 19(82.6) | | | 14(61) | | |
| Acute coronary syndrome | | | | | | | | | | | | |
| No | 9(47.4) | 2.6[0.5-13] | 0.2 | 36(97.3) | 0.1[0.01-2.1] | 0.1* | 19(51.4) | 1.4[0.4-4] | 0.5 | 17(46) | 0.7[0.2-2.6] | 0.7 |
| Yes | 7(70) | | | 13(87.6) | | | 9(60) | | | 6 (40) | | |

| Variables | Insulin-induced lipodystrophy Total=60 | | | Bleeding/bruising Total=96 | | | Injection-pain Total=96 | | | Insulin leakage Total=96 | | |
|--|---|---------------|-------------|-------------------------------|---------------|--------------|----------------------------|---------------|------------------|-----------------------------|---------------|-------------|
| | N (%) | OR [IC] | p | N (%) | OR [IC] | p | N (%) | OR [IC] | p | N (%) | OR [IC] | p |
| Dysthyroidism | | | | | | | | | | | | |
| No | 13 (59.1) | 0.5[0.09-2.9] | 0.4 | 36(94.7) | 0.7[0.06-8.6] | 0.7 | 21(55.3) | 0.8[0.2-2.7] | 0.7 | 18(47.4) | 0.6[0.1-2.1] | 0.4 |
| Yes | 13 (42.9) | | | 13 (93) | | | 7(50) | | | 5(37.7) | | |
| History of surgery | | | | | | | | | | | | |
| No | 26(52) | 2.1[0.5-9.2] | 0.2 | 63 (84) | 0.8[0.7-0.9] | 0.049 | 35 (46.7) | 4.8[1.5-15] | 0.005 | 33(44) | 1.4[0.5-3.7] | 0.4 |
| Yes | 7(70) | | | 21(100) | | | 17 (81) | | | 11(52.4) | | |
| Family history of diabetes | | | | | | | | | | | | |
| No | 26(63.4) | 0.3[0.1-1.2] | 0.05 | 53(86.9) | 1.1[0.3-4.2] | 0.8 | 38(62.3) | 0.4[0.1-0.9] | 0.035 | 34(55.7) | 0.3 [0.1-0.7] | 0.01 |
| Yes | 7(36.8) | | | 31(88.6) | | | 14(40) | | | 10(28.6) | | |
| Tobacco use | | | | | | | | | | | | |
| No | 31 (60.8) | 0.1[0.03-0.9] | 0.03 | 69(85.2) | 0.8[0.7-1.2] | 0.03 | 48(59.3) | 0.2[0.07-0.8] | 0.019 | 39(48.1) | 0.5[0.1-1.7] | 0.2 |
| Yes | 2 (22.2) | | | 15(100) | | | 4(26.7) | | | 5(33.3) | | |
| Type of diabetes | | | | | | | | | | | | |
| Type 1 | 16(45.7) | 2.5[0.8-7.3] | 0.08 | 46(86.8) | 1.1[0.3-3.9] | 0.8 | 24(45.3) | 2.2[0.9-5.1] | 0.052 | 27(51) | 0.6[0.2-1.4] | 0.2 |
| Type 2 | 17 (68) | | | 38(88.4) | | | 28(65.1) | | | 17(39.5) | | |
| Seniority of diabetes | | | | | | | | | | | | |
| < 10 years | 8(50) | 1.3[0.4-4.1] | 0.6 | 19(70.4) | 6.8[1.8-25] | 0.003 | 19(70.4) | 0.3[0.1-1.2] | 0.04 | 15(55.6) | 0.5[0.2-1.4] | 0.2 |
| > 10 years | 25(56.8) | | | 65(94.2) | | | 33(47.8) | | | 29(42) | | |
| Seniority of insulin | | | | | | | | | | | | |
| < 12 years | 17(51.5) | 1.4[0.4-3.8] | 0.5 | 46(85.2) | 1.6[0.4-5.9] | 0.4 | 38(70.4) | 0.2[0.08-0.5] | <0.001 | 30(55.6) | 0.4[0.1-0.9] | 0.03 |
| > 12 years | 16(59.3) | | | 38(90.5) | | | 14(33.3) | | | 14(33.3) | | |
| Total daily dose of insulin | | 0.9 [0.9-1.1] | 0.6 | | 1.1[0.9-1.1] | 0.2 | | 1.1[0.9-1.2] | 0.5 | | 0.9[0.9-1.02] | 0.5 |
| Insulin regimen | | | | | | | | | | | | |
| Basal insulin regimen | 15(57.7) | 0.8[0.2-2.3] | 0.7 | 29(76.3) | 5.7[1.4-22] | 0.008 | 24 (63.2) | 0.5[0.2-1.2] | 0.1 | 22(58) | 0.4[0.2-1.02] | 0.055 |
| Basal/bolus insulin regimen | 18(53) | | | 55(94.8) | | | 28 (48.3) | | | 22(37.9) | | |
| History of hospitalisation for diabetes | | | | | | | | | | | | |
| No | 2(66.7) | 0.5[0.05-7] | 0.6 | 7(77.8) | 2.2[0.4-12] | 0.3 | 5(55.6) | 0.9[0.2-3.7] | 0.9 | 3(33.3) | 1.7[0.4-7.5] | 0.4 |
| Yes | 31(54.4) | | | 77(88.5) | | | 47(54) | | | 41(47.1) | | |
| Haemoglobin A1c level (N=90) | | | | | | | | | | | | |
| <10 | 12(46.2) | 2.4[0.8-7.4] | 0.1 | 36(80) | 5.3[1.1-26] | 0.02 | 29(64.4) | 0.3[0.1-0.8] | 0.02 | 22(48.9) | 0.6[0.2-1.4] | 0.2 |
| >10 | 19(67.9) | | | 43(95.6) | | | 18(40) | | | 17(37.8) | | |
| Device used for injection | | | | | | | | | | | | |
| Syringe | 31(58.5) | 0.2[0.05-1.6] | 0.1 | 72(85.7) | 1.2[1.06-1.2] | 0.16 | 50(59.5) | 0.1[0.02-0.6] | 0.005 | 40(47.6) | 0.5[0.1-2] | 0.3 |
| Pen | 2(28.6) | | | 12(100) | | | 2(16.7) | | | 4(33.3) | | |
| Injection angle | | | | | | | | | | | | |
| 45° | 13(68.4) | 0.4[0.14-1.3] | 0.1 | 28(84.8) | 1.4[0.4-5] | 0.5 | 16(48.5) | 1.4[0.6-3.3] | 0.4 | 14(42.4) | 1.2[0.5-2.8] | 0.6 |
| 90° | 20(48.8) | | | 56(88.9) | | | 36(57.1) | | | 30(47.6) | | |

| Variables | Insulin-induced lipodystrophy Total=60 | | | Bleeding/bruising Total=96 | | | Injection-pain Total=96 | | | Insulin leakage Total=96 | | |
|--|---|----------------|------------------|-------------------------------|---------------|--------------|----------------------------|---------------|--------------|-----------------------------|--------------|--------------|
| | N (%) | OR [IC] | p | N (%) | OR [IC] | p | N (%) | OR [IC] | p | N (%) | OR [IC] | p |
| Changing length of needle | | | | | | | | | | | | |
| No | 27(50) | 1.2[1.04-1.4] | 0.02 | 79(87.8) | 0.7[0.07-6.5] | 0.7 | 46(51.1) | 1.2[1.1-1.3] | 0.03 | 38(42.2) | 1.3[1.1-1.5] | 0.008 |
| Yes | 6(100) | | | 5(83.3) | | | 6(100) | | | 6(100) | | |
| Skin fold before injection | | | | | | | | | | | | |
| No | 11(84.6) | 0.1[0.03-0.8] | 0.015 | 21(95.5) | 0.2[0.03-2.2] | 0.2 | 35(57.4) | 0.7[0.3-1.6] | 0.4 | 9 (41) | 1.3[0.5-3.4] | 0.5 |
| Yes | 22(46.8) | | | 63(85.1) | | | 17(48.5) | | | 35(47.3) | | |
| Rotation of injection sites | | | | | | | | | | | | |
| No | 24(64.9) | 0.3[0.1-0.9] | 0.049 | 53(87) | 1.1[0.3-4.2] | 0.8 | 15(68.2) | 0.4[0.1-1.2] | 0.13 | 28 (46) | 0.9[0.4-2.2] | 0.9 |
| Yes | 9(39.1) | | | 31(88.6) | | | 37(50) | | | 16(45) | | |
| Changing location of injection at same site | | | | | | | | | | | | |
| No | 2 (66.7) | 0.5 [0.05-7] | 0.6 | 8(66.7) | 4.7[1.2-19] | 0.02 | 11(91.7) | 0.08[0.1-0.7] | 0.005 | 6(50) | 0.8[0.2-2.7] | 0.7 |
| Yes | 31(54.4) | | | 76(90.5) | | | 41(48.8) | | | 38(45.2) | | |
| Skin disinfection | | | | | | | | | | | | |
| No | 9(90) | 0.1[0.01-0.8] | 0.009 | 14(87.5) | 1[0.1-5] | 1 | 6(37.5) | 2.2[0.7-6.8] | 0.143 | 5(31.3) | 2[0.6-6.5] | 0.2 |
| Yes | 24(48) | | | 70(87.5) | | | 46(57.5) | | | 39(48.8) | | |
| Using warmed insulin | | | | | | | | | | | | |
| No | 30(75) | 0.07[0.01-0.3] | <0.001 | 56(83.6) | 4.1[0.5-33] | 0.15 | 39(58.2) | 0.7[0.2-1.8] | 0.5 | 28(41.8) | 2.9[1.1-8] | 0.032 |
| Yes | 3(18.8) | | | 21(95.5) | | | 11(50) | | | 15(68.2) | | |
| Skipping injections | | | | | | | | | | | | |
| No | 8(47.1) | 1.5 [0.5-4.8] | 0.4 | 20(74.1) | 4.8[1.3-15] | 0.034 | 8(29.6) | 4.1[1.6-10.9] | 0.003 | 7(26) | 3.3[1.2-8.8] | 0.014 |
| Yes | 25(58.1) | | | 64(92.8) | | | 44(63.8) | | | 37(53.6) | | |

N: number, %: percentage, OR: Odds Ratio, CI: confidence interval

Table 4. Independent factors of insulin injection complications

| Variables | Adjusted OR | 95% CI of Adjusted OR | p |
|---|-------------|-----------------------|--------------|
| 1. Insulin-induced lipodystrophy | | | |
| HBA1C level>10% | 22 | [1.5-30.8] | 0.02 |
| Family history of diabetes | 0.02 | [0.002-0.3] | 0.004 |
| Using warmed insulin | 0.08 | [0.009-0.7] | 0.031 |
| Skin fold before injection | 0.04 | [0.003-0.6] | 0.02 |
| Skin disinfection | 0.005 | [0.001-0.2] | 0.006 |
| 2. Bleeding and/or bruise | | | |
| Skipping injections | 27.6 | [2-38.9] | 0.014 |
| History of chronic disease | 15.4 | [1.3-17.6] | 0.028 |
| Seniority of diabetes > 10 years | 41.2 | [3-56] | 0.005 |
| Haemoglobin A1c level>10 | 10.6 | [1.4-79] | 0.021 |
| 3. Injection-pain | | | |
| Urban area | 0.021 | [0.001-0.4] | 0.01 |
| Dyslipidemia | 19 | [2-187] | 0.012 |
| Surgical history | 20.2 | [1.6-162] | 0.022 |
| Family history of diabetes | 0.075 | [0.008-0.67] | 0.021 |
| Insuline seniority >12 years | 0.086 | [0.01-0.7] | 0.025 |
| 4. Insulin leakage | | | |
| Unmarried patients | 16.4 | [2.1-128] | 0.007 |
| Obese patients | 0.003 | [0.001-0.09] | 0.001 |
| Painful injections | 21.3 | [3.5-130] | 0.001 |
| Insulin-induced lipodystrophy | 18.7 | [2.2-167] | 0.009 |

OR: Odds ratio; CI: Confidence Interval

The median age of participants was 45 years with IQR=[36-60] years. It is a relatively similar compared to the age reported by previous studies [16,17] and younger than another arabic survey finding a mean age of 60 years old [4]. Difference with this Arabic study could be related to their methods which includes community going to the pharmacies to buy their diabetes treatment. For gender, we noted female predominance (61.5%). This was in disagreement with another African study [3] finding male predominance. This difference could be explicated by demographic characteristics of each country.

According to the results of our study, the majority of patients were storing insulin in the refrigerator (96.1%), changing the injection location (87.5%), rotating the injection site (89.5%), doing skin disinfection (83.3%) and skin fold before injecting (77.1%), and keeping syringe under the skin after injection (61.5%). Besides, all diabetic using pen and most diabetic patients using syringe (76.7%) reuse their devices despite the recommendations of manufacturers for the single-use of syringes and needles for insulin administration. Many of patients did not rotate correctly injection site, did not disinfect the syringe before injections, did not penetrate the skin with a right needle angle, did not inject warmed insulin and did not manage

needles in suitable containers. On the other hand, about half patients did not verify the expiration date and the majority of patients skipped their insulin injections. These findings were in line with further studies showing an inadequate level of knowledge among diabetic patients toward their self-administered insulin [16–18].

The ever-present but surprising threat was the non-adherence to single-use of syringes and needles. In fact, in case of an insulin pen, if the needle was not removed between two injections, the air may leak into the injector which could cause wrong dose of insulin injection later [19]. This could explain the high prevalence found of uncontrolled diabetes in about half of our patients.

The huge majority of our insulin-treated patients had at least one complication of insulin injection. Lipodystrophy detected by health-care professionals was noted in more than half of patients. In fact, this prevalence was higher than that found in other surveys finding a prevalence of 37% in Jordan [20], 39.7% in the Kingdom of Saudi Arabia [21] and 43% in a European study [22]. Uncontrolled diabetes by having a high level of HBA1C was an independent factor of

lipodystrophy, this finding was similar to prior research [20,23]. On the other hand, using warmed insulin, skin disinfection and skin fold before injections were independent factors protecting from lipodystrophy. Thus, errors in technique and storage of insulin injection could be responsible for a high rate of lipodystrophy [22]. Subsequently, respecting correct injection technique must protect insulin-treated patients from lipodystrophy.

Among our injectors, more than 45% suffered from bleeding and or bruising, this prevalence was higher than that mentioned in a previous study (33%) [15] but lower than the prevalence found in the Saoudian survey (58.7%) [24]. Having chronic disease was one of the independent factors of this complication. This result was supported by another study assessing the impact of the presence of comorbidities in such complications [24]. A high level of HBA1C was also an independent factor of this complication, which was in line with similar findings [25]. Evidence suggests that seniority of diabetes could lead to higher insulin injections and thus a higher prevalence of injection complications. In this context, seniority of diabetes was an independent factor of bleeding or bruising. The last independent factor of this complication was skipping injections. In fact, because of the cross-sectional type of our study, we could not predict the direction of association between bleeding and skipping injections. The most suitable explanation is that patients skip their injections because of bleeding or bruising.

Injection pain was detected in more than half patients. This prevalence was near to what was found in a recent study [26]. In fact, pain, as a subjective experience not directly observed, could be influenced by social, cultural and psychological factors [27]. Factors we found associated with injection pain were urban area, dyslipidaemia, surgical history, family history of diabetes and insulin seniority. Thus, they could be summarized as patient's experience which is directly involved in the pain experience.

The prevalence of insulin leakage was above 45%. Similar surveys found a lower prevalence of insulin leakage (less than 40%) [26,28]. Being obese was an independent factor associated with a lower prevalence of insulin leakage. This could be explained by the fact that obesity had the potential to influence the extent of distribution of insulin through changes in subcutaneous tissue

composition and depth with lower insulin leakage. In fact, the association between obesity, needle length and insulin leakage was a subject of controversy. There was a long-held belief that diabetic obese patients need longer needle lengths to effectively inject insulin and reduce insulin leakage [29]. However, it seems to be an outdated school of thought and evidence demonstrated that no association between insulin leakage and needle length [29,30] which was proved by our survey. Being unmarried or living alone was also an independent factor of insulin leakage. Other surveys insisted that this situation is well known as a risk factor for non-adherence to insulin injection as well as their complications [31]. Other insulin injection complications such as having painful injections and lipodystrophy were independent factors of insulin leakage. Evidence suggests that these complications are negatively perceived by injectors which could lead to non-adequate injection techniques which subsequently lead to more insulin leakage.

5. CONCLUSION

Through this study, a huge gap between recommendations of insulin administration guidelines and current practice as well as a poor level of knowledge was observed among insulin self-injecting patients. It is important to note that complications of insulin injections, such as lipodystrophy, bleeding or bruising, pain and insulin leakage were common. These adverse effects could be veritable barriers to patient's adherence to treatment regimens involving multiple daily injections. Understanding the present knowledge and practices of self-injecting patients is already a cornerstone to plan well-targeted interventions to improve diabetic patient's care and alleviate the burden of its effects sides. Thus, healthcare providers should pay more attention to therapeutic education on insulin treatment by re-evaluating injection practices at each consultation.

CONSENT

As per international standard or university standard, patient(s) written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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