Patient Preference and Adherence

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ORIGINAL RESEARCH

# Level of Satisfaction Among Patients Using Insulin Administered by Pen vs Vial/Syringe. An Observational Prospective Study

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**Purpose:** To determine the satisfaction of patients with diabetes mellitus who used subcutaneous insulin application devices in Colombia.

**Patients and Methods:** An observational prospective study of patients with diabetes mellitus receiving insulin treatment in Colombia. Sociodemographic, comorbidity and pharmacological data were taken from a drug dispensing database. Through telephone calls, satisfaction with application devices was evaluated with Diabetes Treatment Satisfaction Questionnaire status version (DTSQ-s). Satisfaction was considered high at a score ≥30 points. The change in the type of insulin delivery device (ie, from pen to vial/syringe, and from vial/syringe to pen) was evaluated during a 1-year follow-up.

**Results:** A total of 382 patients from 75 cities were selected, with a median age of 66.0 years, and 56.3% were women, and 65.2% were treated with long-acting insulins. The mean DTSQ-s score was 26.6±5.3 points, and 38.7% presented high satisfaction, without statistically significant differences between pen and vial/syringe. A total of 18.8% changed the administration device, mainly those that came from Bogotá-Cundinamarca (OR:2.19; 95% CI:1.01–4.75), in concomitant treatment with other antidiabetic drugs (OR:2.28; 95% CI:1.00–5.22) and those who previously used insulin in vial/syringe (OR:33.90; 95% CI:11.88–96.74).

**Conclusion:** The participants had low satisfaction with the insulin delivery device. No statistically significant differences were found in satisfaction between those who received pen vs vial/syringe insulin, and patients using the latter had a high probability of switching to insulin pen.

**Keywords:** (MeSH): diabetes mellitus, patient satisfaction, insulin, long-acting, insulin, short-acting, pharmacoepidemiology

## Introduction

Diabetes mellitus (DM) is a growing public health problem.[1,2] It is characterized by hyperglycemia and can lead to morbidity, mortality and reduced quality of life.[1] By 2021, an estimated 537 million people in the world had DM. By 2030, that number is expected to increase to 643 million and by 2045 to 783 million, which constitutes an increase of 46% from 2021 to 2045.[2] In Colombia, the prevalence of DM is 8.3%.[3] Currently, there are between 150 and 200 million patients with DM treated with insulin worldwide.[4] In type 1 DM, insulin is the mainstay of treatment, while in type 2 DM, insulin therapy is used after oral or other injectable medications become inadequate or insufficient to achieve glycemic control.[1,5]

Insulin can be administered efficiently and safely with different devices, the most frequent being injection pens and vials that require syringes.[6] When choosing between pen and vial/syringe, patient or caregiver preferences, cost, type of insulin, dosing regimen, and self-monitoring capabilities should be considered.[7] In general, the pens are easier to use (especially for older adults and children), allow more precise dosing, and have small, thin needle sizes that reduce fear and pain.[4,6,7] The

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Standards of Medical Care in Diabetes (2022) recommend the use of insulin pens for most patients, especially those with dexterity or vision problems, to facilitate the precise administration of the drug.[7]

Compliance with insulin therapy is low, which acts as a barrier to the successful control of glycemia and the management of DM.[6] Adequate satisfaction is related to better adherence and persistence in treatment.[8,9] Satisfaction can be understood as the degree to which a patient considers that the health care service or product or the way in which it is provided is useful, effective or beneficial.[10] This can be quantified in patients with DM using the Diabetes Treatment Satisfaction Questionnaire (DTSQ),[11] which is available in more than 100 languages 9, including Spanish.[12] It is widely used internationally and approved by the World Health Organization (WHO) and the International Diabetes Federation (IDF).[9] The DTSQ can evaluate satisfaction independent of the treatment used (diet, oral antidiabetics or insulin therapy); the questionnaire is short and relatively easy to answer, and the results can be directly compared with those obtained in other countries.[9]

Studies have shown that satisfaction among patients with DM can vary according to sociodemographic and clinical variables and the type of antidiabetic regimen used.[13–15] However, no studies address satisfaction according to the type of insulin delivery device. The Colombian Health System offers universal coverage to the entire population through two affiliated regimes: the contributory one that is paid by workers and employers and the subsidized insurance that covers all people without the ability to pay. The subsidized insurance plan covers a significant number of human and analog insulins in pen and vial/syringe forms. The objective of this study was to determine the level of patients' satisfaction with the subcutaneous insulin application devices available in Colombia.

# Methods

## Study Design, Population and Period

An observational prospective study was carried out on the satisfaction of patients with DM according to the type of insulin application devices they were using. The patients were identified based on a drug dispensing database that collects information from approximately 8.5 million people affiliated with five health insurance companies in the Colombian Health System, representing approximately 30.0% of the population participating in the contributory insurance system and 6.0% of the state-subsidized insurance, which covers 17.3% of the Colombian population.

From this population, patients with DM were selected, using the codes of the International Classification of Diseases, version 10 (ICD-10), codes E100-E149, 0240–0244, and 0249. Participants could be any age or sex, living in any city and using at least one human or similar insulin between August 1 and 31, 2021. During the study period, a total of 70,027 people who met the criteria were identified. For the characterization of the different insulin application devices, all identified patients were considered, while to evaluate satisfaction and other sociodemographic and pharmacological variables, only those ages 18 or older (n=69,356) were included.

## Sample Size Determination and Sampling Technique

The group size was calculated randomly and stratified from 382 cases using the Epi Info program. Stratification was made according to the type of application device (pen or vial/syringe), with an error rate of 5%, a confidence interval of 95% and an expected frequency of 50%.[16]

## Data Collection Procedures

Telephone calls were made to the selected patients, and with prior verbal informed consent, satisfaction was evaluated using the DTSQ-s. Those patients who were on concomitant treatment with insulin pen and vial/syringe were excluded. Each patient was followed and medications dispensed for 1-year or until the patient chose to change his or her insulin application device.

## Study Variables

With the information obtained from the patient and the medicines dispensed by the company Audifarma SA, a database was designed that allowed the following variables to be collected:

- Sociodemographic: sex, age, education, occupation, socioeconomic status, health system affiliation regime (contributory or subsidized) and city of residence. The place of residence was categorized according to the regions of Colombia and considering the classification of the National Administrative Department of Statistics (DANE) of Colombia, as follows: Caribbean region, Central region, Bogotá-Cundinamarca region, Pacific region and Eastern region-Orinoquia-Amazon. Similarly, according to DANE, socioeconomic strata were classified as: stratum 1 (low-low), stratum 2 (low), stratum 3 (medium-low), stratum 4 (medium), stratum 5 (medium-high and stratum 6 (high).
- Comorbidities: These conditions were identified from the main and secondary diagnoses reported by the ICD-10 in the selected patients.
- Pharmacological:
- Insulin: human (crystalline and NPH) or analogous (short-acting: aspartate, glulisine or lispro; long-acting: glargine, detemir or degludec), dose used in units per day, insulin therapy scheme (basal, basal-bolus or bolus), application device (pen or vial/syringe), counseling at the time of insulin initiation (yes/no) and type of professional who performed the counseling (general practitioner, internist/endocrinologist, nurse, others).
- Other antidiabetic drugs: biguanides (metformin), sodium/glucose cotransporter inhibitors -SGLT2i- (empagliflozin, dapagliflozin or canagliflozin), dipeptidyl peptidase type 4 inhibitors -iDPP4- (linagliptin, saxagliptin, sitagliptin or vildagliptin), sulfonylureas (glibenclamide, glimepiride or gliclazide), glucagon-like peptide 1 -GLP1- analogs (liraglutide, exenatide, semaglutide or dulaglutide).
- Satisfaction: Satisfaction was evaluated using the Diabetes Treatment Satisfaction Questionnaire status version (DTSQ-s), which consists of eight sections, each of which allows seven possible responses that range from 0 (very dissatisfied) to 6 (extremely satisfied). The overall satisfaction score is obtained by adding 6 items of the questionnaire (satisfaction with current treatment, convenience of treatment, flexibility, knowledge about diabetes, recommendation of therapy, desire to continue with therapy), so it can vary from very satisfied (36 points) to very dissatisfied (0 points). The two remaining sections are evaluated separately and measure the frequency of hyperglycemia and hypoglycemia perceived by the patient. Scores range from 0 (they never perceive it) to 6 (almost all the time).[11,12] High satisfaction was measured as 30 or more points on the DTSQ-s.[17]
- Comedications: These were grouped into the following categories: a) antiplatelet agents, b) antihypertensives and diuretics, c) lipid-lowering drugs; d) antiulcer drugs, e) antidepressants, f) anxiolytics and hypnotics, g) thyroid hormone, h) antipsychotics, i) anticonvulsants, j) antihistamines, k) analgesics and anti-inflammatories, l) anticoagulants, among others.

## Ethical Statement

The protocol was approved by the Bioethics Committee of the Technological University of Pereira in the category of research without risk (Endorsement code: 37–030521 of May 5 of 2021). The ethical principles established by the Declaration of Helsinki were respected. Oral informed consent was acquired prior to the interview by telephone. Risk-free research, in which only questions related to health status are asked according to Colombian legal regulations (Resolution 8430 of 1993 of the Ministry of Health) do not require written consent and this can be obtained verbally. The bioethics committee approved obtaining verbal consent.

## Data Entry and Analysis

The data were analyzed with the statistical package SPSS Statistics, version 26.0 for Windows (IBM, USA). A descriptive analysis was performed with frequencies and proportions for the qualitative variables and measures of central tendency and dispersion for the quantitative variables. The comparison of quantitative variables was performed using Student's t tests or Mann–Whitney *U*-tests and $X^2$ or Fisher's exact test for categorical variables. Multivariate binary logistic regression models were developed that included the associated variables in the bivariate analyses, as well as those with sufficient plausibility or reported association to identify those that could be related to having high satisfaction (DTSQ-s: ≥30 points) (yes/no) and a change in insulin application device (yes/no). A level of statistical significance was established at $p < 0.05$.

# Results

## Sociodemographics

A total of 70,027 patients with insulin prescriptions were identified. Of these, the majority used insulin analogs (n=67,656; 96.6%), especially long-acting insulin (n=66,026; 94.3%), followed by short-acting insulin (n=29,255; 41.8%). Human insulin was used in 3.8% (n=2639) of the patients. The pharmaceutical forms in pen predominated (n=66,983; 95.7%), while the pharmaceutical forms in vial/syringe were used in fewer patients (n=3662; 5.2%).

A total of 382 patients who were selected in the stratified randomized sampling came from 75 different cities and reflect the characteristics of the population (Supplementary Table 1). 56.3% (n=215) were women, and the median age was 66.0 years (interquartile range: 58.0–74.0 years; range: 18.0–98.0 years). Patients who were 65 years or older were 55.5% (n=212). Most of the patients came from the Pacific region (n=123, 32.2%), followed by the Central region (n=111, 29.1%) and Bogotá-Cundinamarca region (n=89, 23.3%), the Caribbean region (n=40; 10.5%) and the Eastern-Orinoquía-Amazon region (n=19; 5.0%). Most participants had primary school education (n=211; 55.2%) followed by secondary school education (n=107; 28.0%); the main occupation was household activities (n=123; 32.2%), they were pensioners (n=67; 17.5%) or unemployed (n=45; 11.8%), and the majority had low incomes (n=214; 56.0%). A total of 80.6% (n=308) of the patients participated in the contributory insurance program, and 19.4% (n=74) participated in the subsidized insurance program.

## Comorbidities

The main comorbidities that were identified were hypertension (n=296, 77.5%), followed by hypothyroidism (n=84, 22.0%), chronic kidney disease (n=55, 14.4%), dyslipidemia (n=25; 6.5%) and anxiety disorders (n=24; 6.3%). A total of 20.7% (n=79) of the patients had chronic complications related to DM. The main complications were chronic kidney disease (n=55; 14.4%), atherosclerotic coronary disease (n=15; 3.9%) and peripheral neuropathy (n=10; 2.6%). The vast majority also received medications other than antidiabetics (n=338; 88.5%), which were mainly antihypertensive drugs and diuretics (n=264; 69.1%), lipid-lowering drugs (n=243; 63.6%), antiplatelet drugs (n=164; 42.9%), analgesics and anti-inflammatories (n=138; 36.1%) and anti-ulcer medications (n=133; 34.8%).

## Treatment of Diabetes Mellitus, Application Devices and Satisfaction

The most used insulin was glargine (n=254; 66.5%), followed by glulisine (n=86; 22.5%), NPH (n=84; 22.0%), degludec (n=24; 6.3%), aspartate (n=19, 5.0%), crystalline (n=17, 4.5%), lispro (n=11, 2.9%) and detemir (n=10, 2.6%). Most participants were in treatment with only a long-acting insulin (n=249; 65.2%). The average dosages in units of insulin per day were similar between pen and vial/syringe users (31.3 IU vs 32.5 IU; p=0.556). A total of 95.3% (n=364) of the patients had a glucometer at home. A total of 90.8% (n=347) of the patients stated that they received counseling when they began treatment with insulin, provided by general practitioners (n=223; 58.4%), nurses (n=87; 22.8%) and internists or endocrinologists (n=41; 10.7%). A total of 81.9% (n=313) of the patients received other concomitant anti-diabetic medications, mainly biguanides (n=244, 63.9%), iDPP4 (n=173, 45.3%), and SGLT2i (n=127, 33.2%), GLP-1 analogs (n=21, 5.5%) and sulfonylureas (n= 3, 0.8%) (Table 1).

According to the DTSQ-s questionnaire, the average score was 26.6±5.3 (range:8–36 points), and 38.7% (n=148) presented high satisfaction (≥ 30 points), with no statistically significant differences found between those who used pen or vial/syringe. Most of the time, 10.2% (n=39) and 4.9% (n=19) of the patients declared that their glycemia had been unacceptably high or low, respectively. Table 2 shows the score for each question on the DTSQ-s, according to the type of insulin application device.

## Multivariate Analysis

The bivariate and multivariate analyses did not find any variable related to increasing or decreasing the probability of having high satisfaction (Supplementary Table 2). However, during the year of follow-up, 18.8% (n=72) of the patients changed their type of insulin application device. A total of 93.1% (n=67/72) changed from vial/syringe to pen and 6.9% (n=5) from pen to vial/syringe. The binary logistic regression – adjusted for sociodemographic, pharmacological and

**Table 1** Comparison Between Subcutaneous Insulin Application Devices in Patients with Diabetes Mellitus, Colombia

| Variables | Pen | | Vial/syringe | | p |
|---|---|---|---|---|---|
| | n=191 | % | n=191 | % | |
| Women | 109 | 57.1 | 106 | 55.5 | 0.757 |
| Age, median (Interquartile range) | 65.0 (58.0–74.0) | | 66.0 (59.0–74.0) | | 0.927[a] |
| Comorbidities | – | – | – | – | – |
| Arterial hypertension | 151 | 79.1 | 145 | 75.9 | 0.462 |
| Hypothyroidism | 39 | 20.4 | 45 | 23.6 | 0.459 |
| Chronic kidney disease | 20 | 10.5 | 35 | 18.3 | 0.029 |
| Dyslipidemia | 14 | 7.3 | 11 | 5.8 | 0.535 |
| Anxiety disorders | 15 | 7.9 | 9 | 4.7 | 0.206 |
| Received advice on insulin | – | – | – | – | – |
| Yes | 173 | 90.6 | 174 | 91.1 | 0.859 |
| No | 18 | 9.4 | 17 | 8.9 | |
| Type of professional who gave the advice | – | – | – | – | – |
| General practitioner | 113 | 59.2 | 110 | 57.6 | 0.756 |
| Internist or endocrinologist | 26 | 13.6 | 15 | 7.9 | 0.069 |
| Nurse | 37 | 19.4 | 50 | 26.2 | 0.113 |
| Drugs | – | – | – | – | – |
| Analog insulins | 188 | 98.4 | 106 | 55.5 | <0.001 |
| Human insulins | 3 | 1.6 | 86 | 45.0 | <0.001[b] |
| Insulin units day | | | | | |
| Mean (standard deviation) | 31.3 (19.0) | | 32.5 (19.2) | | 0.556[c] |
| Median (Interquartile range) | 26.5 (18.0–38.0) | | 30.0 (19.0–40.0) | | 0.548[a] |
| Treatment schemes | – | – | – | – | – |
| Long-acting insulin | 115 | 60.2 | 134 | 70.2 | 0.041 |
| Long-acting + short-acting insulin | 74 | 38.7 | 49 | 25.7 | 0.006 |
| Short-acting insulin | 2 | 1.0 | 8 | 4.2 | 0.105[b] |
| Other antidiabetics | 166 | 86.9 | 147 | 77.0 | 0.012 |
| Metformin | 130 | 68.1 | 114 | 59.7 | 0.088 |
| Dipeptidyl peptidase 4 inhibitors | 88 | 46.1 | 85 | 44.5 | 0.758 |
| Sodium-glucose Cotransporter-2 inhibitors | 80 | 41.9 | 47 | 24.6 | <0.001 |
| Glucagon-like peptide analogues | 17 | 8.9 | 4 | 2.1 | 0.006[b] |
| Sulfonylureas | 1 | 0.5 | 2 | 1.0 | 1.000[b] |
| Comedications | – | – | – | – | – |
| Antihypertensives and diuretics | 132 | 69.1 | 132 | 69.1 | 1.000 |
| Lipid-lowering | 131 | 68.6 | 112 | 58.6 | 0.043 |
| Antiplatelet agents | 77 | 40.3 | 87 | 45.5 | 0.301 |
| Analgesics and anti-inflammatories | 69 | 36.1 | 69 | 36.1 | 1.000 |
| Antiulcer | 68 | 35.6 | 65 | 34.0 | 0.747 |

**Notes**: [a]mann–Whitney *U*-test; [b]Fisher's exact test; [c]Student's *t*-test.

comorbid variables – found that patients who came from the Bogotá-Cundinamarca region with concomitant prescriptions for other anti-diabetic drugs, and especially those who were being managed with insulins that were applied by vial/syringe, had a greater probability of changing the delivery device. No variable reduced the risk (Hosmer–Lemeshow test p=0.967 and area under the curve =0.849) (Table 3).

**Table 2** Comparison of Satisfaction Between Types of Insulin Application Devices, in Patients with Diabetes Mellitus, Colombia

| Diabetes Treatment Satisfaction Questionnaire | Total (n=382) | | Pen | | Vial/syringe | | p[a] | p[b] |
|---|---|---|---|---|---|---|---|---|
| | Mean (SD) | Median (IQR) | Mean (SD) | Median (IQR) | Mean (SD) | Median (IQR) | | |
| How satisfied are you with your current treatment? | 4.7 (1.1) | 5.0 (4.0–5.0) | 4.7 (1.1) | 5.0 (4.0–5.0) | 4.8 (1.1) | 5.0 (4.0–6.0) | 0.449 | 0.310 |
| How often have you felt that your blood sugars have been unacceptably high recently? | 2.7 (1.3) | 3.0 (2.0–4.0) | 2.8 (1.4) | 3.0 (2.0–4.0) | 2.7 (1.2) | 3.0 (2.0–3.0) | 0.618 | 0.387 |
| How often have you felt that your blood sugars have been unacceptably low recently? | 2.2 (1.3) | 2.0 (1.0–3.0) | 2.2 (1.3) | 2.0 (1.0–3.0) | 2.1 (1.2) | 2.0 (1.0–3.0) | 0.354 | 0.367 |
| How convenient have you been finding your treatment to be recently? | 4.2 (1.3) | 5.0 (3.0–5.0) | 4.4 (1.1) | 5.0 (4.0–5.0) | 4.0 (1.5) | 4.0 (3.0–5.0) | 0.010 | 0.042 |
| How flexible have you been finding your treatment to be recently? | 3.7 (1.5) | 4.0 (3.0–5.0) | 4.0 (1.2) | 4.0 (3.0–5.0) | 3.4 (1.7) | 4.0 (2.0–5.0) | 0.001 | 0.024 |
| How satisfied are you with your understanding of your diabetes? | 4.2 (1.5) | 5.0 (3.0–5.0) | 4.0 (1.5) | 4.0 (3.0–5.0) | 4.4 (1.5) | 5.0 (3.0–6.0) | 0.018 | 0.006 |
| Would you recommend this form of treatment to someone else with your kind of diabetes? | 4.9 (1.4) | 5.0 (4.0–6.0) | 5.1 (1.2) | 5.0 (5.0–6.0) | 4.8 (1.5) | 5.0 (4.0–6.0) | 0.048 | 0.146 |
| How satisfied would you be to continue with your present form of treatment? | 4.8 (1.1) | 5.0 (5.0–5.0) | 4.9 (0.9) | 5.0 (5.0–5.0) | 4.8 (1.2) | 5.0 (4.0–6.0) | 0.249 | 0.914 |
| Total | 26.6 (5.3) | 28.0 (23.0–31.0) | 27.0 (4.9) | 28.0 (24.0–31.0) | 26.1 (5.7) | 27.0 (22.0–31.0) | 0.124 | 0.262 |
| High satisfaction ≥30 points (n /%) | 148 | 38.7 | 77 | 40.3 | 71 | 37.2 | 0.529[c] | |

**Notes**: [a]mann–Whitney *U*-test; [b]Student's *t*-test; [c]Chi square.
**Abbreviations**: SD, Standard Deviation; IQR, Interquartile Range.

**Table 3** Binary Logistic Regression on the Variables Associated with the Change of Insulin Administration Device, in Patients with a Diagnosis of Diabetes Mellitus, Colombia

| Variables | Sig. | OR | 95% CI | |
|---|---|---|---|---|
| | | | Lower | Upper |
| Ftable | | | | |
| Woman | 0.654 | 1.155 | 0.615 | 2.170 |
| Age (continuous) | 0.066 | 1.027 | 0.998 | 1.056 |
| Bogota-Cundinamarca Region | 0.046 | 2.196 | 1.014 | 4.753 |
| University education | 0.205 | 2.003 | 0.684 | 5.866 |
| Low incomes | 0.684 | 0.874 | 0.458 | 1.670 |
| Arterial hypertension | 0.133 | 1.812 | 0.834 | 3.935 |
| Chronic complications of diabetes mellitus | 0.089 | 0.495 | 0.220 | 1.115 |
| Use of other antidiabetics | 0.049 | 2.288 | 1.002 | 5.223 |
| Lipid-lowering drugs | 0.970 | 0.988 | 0.528 | 1.851 |
| Insulins applied by vial/syringe | <0.001 | 33.907 | 11.884 | 96.744 |
| Human insulin | 0.492 | 0.795 | 0.414 | 1.528 |
| High satisfaction (DTSQ-s: ≥30 points) | 0.093 | 0.578 | 0.305 | 1.096 |

**Abbreviations**: Sig, Statistical significance; OR, Odds Ratio; CI, Confidence interval.

## Discussion

This analysis made it possible to identify the types of subcutaneous insulin application devices, the level of satisfaction and the factors related to changing the insulin device in a group of patients with DM treated in different geographic regions of Colombia. These findings can be useful for health care, academic and scientific personnel in making decisions regarding the opinions, preferences and satisfaction that users expressed about the type of insulin application device they use daily for the management of this pathology.

Most patients received insulin analogs, which is consistent with what was reported in a large study on trends in the use of insulin in patients with type 2 DM in the United States (86.3%).[18] The reason for their wide use may be because insulin analogs have a pharmacokinetic profile close to the physiological action of insulin, so they could provide better metabolic control, less hypoglycemia and greater flexibility.[19,20] Different meta-analyses have not shown a clear benefit of analog insulin over human insulin in terms of mortality, microvascular or macrovascular complications.[21,22] Regarding the risk of severe hypoglycemia, a meta-analysis showed that long-acting insulin analogs were associated with a lower incidence of severe hypoglycemia than NPH insulin.[22] Another meta-analysis compared short-acting insulin analogs with crystalline insulin and found no difference in the risk of hypoglycemia.[21] The 2022 consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) does not provide guidance on the type of insulin to be used in patients with type 2 DM,[1] However, the cost of insulin analogs is considerably higher than that of human insulin.[23]

Similarly, in this report, it was found that insulin pens were the most widely used device, which is in line with current recommendations.[7] The Colombian Health System includes the different human and analog insulins, as well as administration devices in vial/syringe and pen.[24] Since 2006, pen administration devices have been approved for marketing in the country.[25] Doctors have the autonomy to prescribe the type of treatment they consider relevant and their decisions are supported by the Colombian clinical practice guide for the diagnosis, treatment and monitoring of diabetes mellitus, which in turn are based on the ADA guidelines.[26] In the United States, Sarkar et al[18] documented that between 2016 and 2020, there was an increase of 67.2% in the use of insulin pens, which represented 58.7% of all insulin dispensations for the patient year 2020. The introduction of insulin pens increased simplicity, convenience, discretion and dosing precision.[4,7,20] Some studies have shown that patients managed with insulin pens have better results in terms of glycated hemoglobin change, hypoglycemia, adherence and persistence of use compared to vial/syringe application.[6,27] However, in this study, there was no difference in satisfaction between patients treated with an insulin pen and those who used a vial/syringe.

The average satisfaction of patients measured by the DTSQ questionnaire was 26.6 points, which is very similar to that found in Spain and Saudi Arabia, among patients with type 2 DM treated with insulin (26.5 and 27.0 points, respectively).[14,28] In other reports, satisfaction was higher.[15,29] In a study carried out in eight European countries, the average satisfaction was 28.5 points (range 25.9–30.1),[15] while in Argentina, it was 30.0 points.[29] Satisfaction with treatment is a crucial element that is related to better compliance with metabolic goals.[8] Similarly, some studies have reported on different factors related to poor satisfaction, such as older age, female sex, poor metabolic control, the type of treatment received, complications, and the presence of comorbidities.[13–15] In this report, no independent variables were found to be related to satisfaction with insulin treatment. These findings may suggest that patients do not have high satisfaction with their insulin therapy, regardless of the device used for its administration.

When comparing patient satisfaction according to the type of insulin application device, no statistically significant differences were found. However, some criteria of the DTSQ questionnaire were evaluated significantly better in the group of patients treated with pen insulins. Convenience and flexibility were better with pen devices compared to vial/syringe, which is consistent with what has been reported in the literature.[4,7,30] Pen devices allow more precise dosing, are more comfortable to use, are more suitable for people with vision problems or motor dexterity problems, and the device is more discreet for insulin application.[4,7,30] Despite an intense search, it was not possible to find other studies that made this type of comparison, but studies that made other comparisons were identified.[13–15,28,29] For example, AlSlail et al[28] described that patients treated with basal insulin regimens had greater satisfaction than those who received premixed insulin, while Boels et al[15] did not find significant differences according to the insulin regimen used, and Pichon-Riviere et al[29] found no differences in general satisfaction between insulin glargine and NPH users. On the other hand, in different reports, it was documented that patients treated with nonpharmacological measures and with oral medications had greater satisfaction than those treated with insulin regimens.[13–15]

Some variables were significantly associated with the change of insulin administration device. It was found that patients who were being treated with insulin in a vial/syringe had a high probability of switching to pen during follow-up. These findings are consistent with what was found in different studies where persistence was higher among pen insulin users.[31–33] In the United States, two studies showed that persistence was significantly higher and prolonged in patients who started insulin glargine administration via pen compared to those who started with a vial/syringe.[31,33] However, in Singapore, users of insulin

in prefilled pens were more persistent with the therapy compared to users of insulin in vials/syringes.[32] Patients treated in the Bogotá-Cundinamarca region were more likely to change insulin delivery devices. This may be due to the different prescribing habits of doctors, their academic training and even variations in the availability of medicines in each region.[34–36] These differences have also been documented in other pharmacoepidemiological studies carried out in the country.[34–36] Finally, concomitant use of other antidiabetic agents also increased the likelihood of switching insulin delivery devices. These patients are likely to require further intensification of antidiabetic therapy to achieve metabolic goals, so pen devices would have some advantages over vial/ syringe.[27] Even pens have shown better results in the mean reduction of glycosylated hemoglobin, lower hypoglycemia and better adherence and persistence compared to the vial/syringe.[27] Therefore, due to the advantages that pens have over vials/syringes and the high frequency of cases that change from vials/syringes to pens, it can be inferred that the use of pen insulin devices will continue to grow, and with it the treatment costs of patients with DM.[7,23,27] However, if patient adherence to insulin regimens is improved, this will impact on better metabolic control (reduction of glycosylated hemoglobin) and fewer microvascular and macrovascular complications.[1,7,27]

Some limitations should be considered when interpreting the results, since access to the medical records was not obtained to verify the accuracy of the diagnoses assigned by the doctor; they were validated with the patients via telephone call. In addition, there was no information on paraclinical variables, such as glycosylated hemoglobin or glycemia, or on clinical variables other than comorbidities. There was no discrimination between disposable or reusable insulin pens. Similarly, any drugs prescribed outside the health system or not delivered by the dispensing company that patients may have received are unknown. However, the study included a significant number of patients distributed throughout all geographic regions of the national territory, representative of the two main affiliated regimes of the country's health system. Finally, it is necessary to continue conducting studies that evaluate patient satisfaction with insulin management, ideally through studies with prospective designs.

## Conclusions

We can conclude that in this group of patients, the majority were not highly satisfied with the treatment received. No statistically significant differences were found in satisfaction between those who received the pen vs vial/syringe insulin, and the latter had a high probability of switching to insulin pen. However, some items assessed with the DTSQ-s questionnaire were more favorable in the group of patients who received insulins through pen devices. This, added to the high probability of switching from insulin vial/syringe to insulin pen, suggests that these devices should be preferred for the pharmacological management of patients with DM. Future research should address satisfaction among insulin delivery devices in much larger samples. In addition, other factors such as patient beliefs, sociocultural conditions, lifestyles, adherence and clinical outcomes (eg metabolic control, cardiovascular morbidity and mortality and adverse events) should be considered in the analysis.

## Data Sharing Statement

protocols.io. DOI: dx.doi.org/10.17504/protocols.io.261ge3jy7l47/v1 (Private link for reviewers: https://www.protocols.io/private/6280B8F0B6EA11EDAD7F0A58A9FEAC02 to be removed before publication).

## Informed Consent Statement

All patients gave their informed consent to participate, which was recorded in the electronic recording material of the telephone call. Said consent was approved by the bioethics committee.

## Ethics Approval and Consent to Participate

The protocol was approved by the "Bioethics Committee of the Technological University of Pereira" in the category of research without risk (Endorsement code: 37-030521 of May 5 of 2021). The ethical principles established by the Declaration of Helsinki were respected. Oral informed consent was acquired prior to the interview by telephone. Risk-free research, in which only questions related to health status are asked according to Colombian legal regulations (Resolution 8430 of 1993 of the Ministry of Health) do not require written consent and this can be obtained verbally. The bioethics committee approved obtaining verbal consent.

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## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

All the authors declare no conflicts of interest.

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