A Pan-European and Canadian Prospective Survey to Evaluate Patient Satisfaction with the SoloSTAR Insulin Injection Device in Type 1 and Type 2 Diabetes

Nicolae Hancu, M.D., Ph.D.,[1] Leszek Czupryniak, Ph.D.,[2] Elisabeth Genestin, M.D.,[3] and Harald Sourij, M.D.[4]

Abstract

Objective:

This study evaluated patient satisfaction with SoloSTAR® (sanofi-aventis), a prefilled insulin pen device for injection of insulin glargine or insulin glulisine.

Methods:

This was a 6–8-week multicenter (n = 652), observational, prospective Pan-European and Canadian registry study in patients with diabetes mellitus (n = 6542) who recently switched to or started treatment with insulin glargine and/or insulin glulisine using SoloSTAR or were insulin naïve. At the baseline visit, patients were asked to evaluate their satisfaction with their previous device, if applicable. After 6–8 weeks of SoloSTAR use, patients were asked to rate their satisfaction.

Results:

Overall, 6481 patients (mean age 54 years, 48.7% male, 72% type 2 diabetes) were analyzed in this study. Of these, 4995 (77.1%) patients had used insulin before the study and 1641 (32.9%) and 3395 (68.0%) patients had previously used prefilled and/or reusable pens, respectively. During the study, SoloSTAR was used to administer insulin glargine and/or insulin glulisine by 97.3% and 36.0% of patients, respectively (both: 27.0%). Most patients rated SoloSTAR as "excellent/good" for ease of use (97.9%), learning to use (98.3%), selecting the dose (97.6%), and reading the dose (95.1%). Most patients rated ease of use (88.4%) and injecting a dose (84.5%) with SoloSTAR as "much easier/easier" versus their previous pen. Overall, 98% planned to continue using SoloSTAR. No safety concerns were reported.

Conclusion:

This European and Canadian survey shows that SoloSTAR was well accepted in this large patient population. Most patients preferred SoloSTAR to their previous pen and planned to continue SoloSTAR use.

J Diabetes Sci Technol 2011;5(5):1224-1234

Author Affiliations: [1]University of Medicine, Cluj-Napoca, Romania; [2]Diabetology and Metabolic Diseases Department, Medical University of Lodz, Lodz, Poland; [3]sanofi-aventis, Paris, France; and [4]Division of Endocrinology and Metabolism, Medical University of Graz, Graz, Austria

Abbreviations: (SD) standard deviation, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus, (TEAE) treatment-emergent adverse event

Keywords: European, insulin glargine, insulin glulisine, insulin pen device, patient satisfaction, SoloSTAR

Corresponding Author: Nicolae Hancu, M.D., Ph.D., Clinicilor Street no 2-4, 400006 Cluj Napoca, Romania; email address nhancu@umfcluj.ro

Insulin pen devices are generally perceived by patients as being more convenient, flexible, and socially acceptable methods for administering insulin compared with traditional vial and syringe systems.[1–4] As a result, prefilled and disposable pens are now the predominant method for injecting insulin in many countries among patients with type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM). Nevertheless, the use of the vial and syringe still prevails in countries such as Brazil, India, and the United States[5] due, in part, to the perceived cost of using insulin pens relative to the vial and syringe. This is despite evidence showing that the overall treatment costs incurred by patients using insulin pens are lower than in those who use the vial and syringe, as a consequence of the lower rate of hypoglycemia associated with insulin pen use[3,6] and the higher rates of adherence to treatment that are achieved with insulin pens.[7]

In addition to the perceived convenience, flexibility, and social acceptability, insulin pens are able to accurately administer the required doses of insulin, as demonstrated in studies performed by trained research staff and by patients after receiving appropriate training for the device.[8–12] However, there are some additional features that could further improve these devices for patients. Practical aspects of insulin injection pen devices for people with diabetes include the ability to hear and feel clicks when dialing a dose, easy dialing and delivery, ease of performing safety tests, and overall ease of use and cartridge replacement in reusable pens. Specific features that may be attractive to pen users include insulin pens with higher maximum doses to reduce the need for split-dose injections (most pens have a dose limit of 60 U), reduced injection force and dial extension, and improved device differentiation, since most of the existing devices have little scope for differentiating between the different types of insulin to be injected, aside from the product label. Both reduced manual dexterity and visual impairments are common in people with diabetes, with up to 58% of people with diabetes having limited hand joint mobility[13] and 16 million people with diabetes in the United States predicted to have diabetic retinopathy by 2050.[14] In the United States, retinopathy accounts for approximately half of all cases of visual impairment among people with diabetes older than 50 years.[15] Visual impairment in people with diabetes is also frequently associated with other advanced age-related conditions, including macular degeneration, glaucoma, and cataracts.[16]

SoloSTAR® is a novel insulin device approved for the administration of the long-acting insulin, insulin glargine (LANTUS®), or the rapid-acting insulin, insulin glulisine (Apidra®), all manufactured by sanofi-aventis for the treatment of T1DM or T2DM. SoloSTAR offers a higher maximum dose than many of the other insulin pens already available (80 U) and offers product differentiation by the use of different body colors for insulin glargine and insulin glulisine. This should be beneficial for patients with T1DM who are likely to use a basal and a bolus insulin as well as for the increasing number of patients with T2DM who are on basal–bolus regimens. Previous studies have demonstrated the dose accuracy,[10,11] low injection force,[8] and patient preference for SoloSTAR versus other prefilled insulin pen devices.[17] The clinical acceptance of SoloSTAR with insulin glargine has been examined in an observational survey in Australia,[18] showing that health care professionals consider it easy to educate people with diabetes on the use of the pen and consider the pen easy for people with diabetes to use. However, the clinical acceptance and patient satisfaction with SoloSTAR using insulin glargine and/or insulin glulisine have been examined only in Australian patients with diabetes,[19] not yet in European or North American patients. Therefore, in this study, the authors investigated acceptance and patient satisfaction with SoloSTAR in Canada and 12 European countries.

Methods

Study Objectives

The objective of this study was to investigate patient satisfaction with SoloSTAR in people using insulin glargine and/or insulin glulisine in everyday clinical practice.

Study Design

This was a 6–8-week, multinational (Austria, Canada, Denmark, Greece, Hungary, Latvia, The Netherlands, Poland, Romania, Slovenia, Slovakia, Sweden, and the United Kingdom), multicenter (n = 645), open, prospective, observational product/device registry study performed between January 14, 2008, and April 4, 2009. The study was performed in accordance with the principles and all subsequent amendments of the declaration of Helsinki, in compliance with the guidelines for good

STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.[20] All patients provided informed consent to participate in the study.

Study Population

Patients with T1DM or T2DM aged >18 years were enrolled. Subjects were eligible if they were current insulin users with prior disposable or reusable pen experience, or were insulin-naïve subjects on oral medications who were considered by their health care provider to be candidates for starting injectable insulin therapy. Exclusion criteria were current addiction to or abuse of alcohol and/or drugs, diagnosis of dementia, severe visual or dexterity impairment, or a mental condition rendering subjects unable to understand the nature, scope, and possible consequences of the study. Also excluded from the study were subjects who were considered to be uncooperative by the investigators and unlikely either to comply with the study or to reply honestly to the questionnaire or who had a concomitant disease or concomitant medication that may have interfered with their ability to participate in the study.

Study Protocol

The study consisted of two visits. At the initial registry visit (visit 1), patients were switched to, or started on, insulin therapy with LANTUS SoloSTAR for insulin glargine and/or Apidra SoloSTAR for insulin glulisine. For regulatory reasons, patients in Greece and Romania could be treated with SoloSTAR for no more than 15 days before the study to be considered eligible. All patients in Sweden were to be using SoloSTAR before inclusion. All treatment decisions were made in accordance with local clinical practice, and it was entirely at the physician's discretion whether to use insulin glargine, insulin glulisine, or both.

At visit 1, patients completed a questionnaire surveying their prior experience with insulin pens, if applicable, and their demographic and clinical characteristics were also assessed. After 6–8 weeks of SoloSTAR use as part of everyday clinical practice, patients completed a second questionnaire (visit 2) to document their experience and determine their acceptance of SoloSTAR. For patients who used an insulin pen before inclusion, acceptance of SoloSTAR was compared to the pen used before the study. In addition, the following information was collected: person who gave the insulin injection; use of other insulin pen before SoloSTAR; type of insulin used; start of SoloSTAR use the day patient received the supply; if patient did not start using SoloSTAR the day he or she received it, number of days after; whether patient was still using SoloSTAR; if patient was not still using SoloSTAR, number of days since he/she stopped; number of SoloSTAR pens used; disability or other restrictions; frequency of use of a new needle; frequency of safety test; brand of needles with SoloSTAR; face-to-face training on the use of SoloSTAR; confidence in the use of the pen after the training; and number of days to be confident in the use of SoloSTAR.

Treatment-emergent adverse events (TEAEs), possibly related TEAEs, and serious TEAEs were analyzed. Treatment-emergent adverse events are adverse events beginning between the first use of the SoloSTAR pen and the last use of SoloSTAR pen plus 7 days for SoloSTAR with insulin glargine and plus 2 days for SoloSTAR with insulin glulisine. For patients who were treated with SoloSTAR before inclusion in the study, TEAEs were counted from date of inclusion.

Study End Points

The primary end point was patient evaluation of the SoloSTAR pen. The following items (answered with excellent, good, acceptable, poor, or very poor) were described to evaluate the SoloSTAR pen: ease of selecting the dose; ease of correcting a misdialed dose; ease of reading the insulin dose; ease of feeling and hearing dialing clicks; force or effort needed to inject insulin; smoothness or gentleness of injection; ease of knowing that injection was completed or desired dose was delivered; ease of reading how much insulin remained in the cartridge; ease of differentiating the LANTUS SoloSTAR from the Apidra SoloSTAR, for patients using both; ease of learning how to use SoloSTAR; ease of use of SoloSTAR in general; overall assessment of SoloSTAR pen; plan to continue to use SoloSTAR (yes or no); and whether the patient would recommend SoloSTAR (yes or no).

Secondary end points were acceptance of individual pen features; insulin daily dose injected; number of daily injections; confidence in managing the pen or condition; occurrence of pen defects spontaneously reported by users; satisfaction with the previous pen, if appropriate, and comparison between SoloSTAR and the previous pen; and adverse events, including hypoglycemia (adverse events were recorded and coded using MedDRA version 8).

There was no formal sample size calculation for this observational study; however, the authors planned to recruit approximately 6900 patients across 645 centers distributed in 13 countries. The primary outcomes were evaluated using chi-squared tests for the overall population and for subgroups of patients according to age, diabetes type, prior history of using insulin and insulin pens, and whether the patient performed safety tests. Logistic regression was also performed to identify factors predicting satisfaction with SoloSTAR. Secondary outcomes and adverse events were assessed using appropriate summary statistics, with means ± standard deviation (SD) for continuous variables and *n* (%) for categorical variables. Factors recorded by questionnaire at visits 1 and 2 were

Results

Baseline Characteristics

A total of 6542 patients were enrolled in this registry (6528 eligible; 14 excluded owing to missing age or that they did not have T1DM or T2DM). Of these, 6364 were included in the assessment of patient satisfaction and 6481 were included in the safety population (**Figure 1**): mean ± SD age of 54.3 ± 14.5 years, 48.7% were male, and 72.0% had T2DM. Overall, 164 patients were excluded from the patient satisfaction population for the following reasons: no insulin injections with SoloSTAR (*n* = 47),

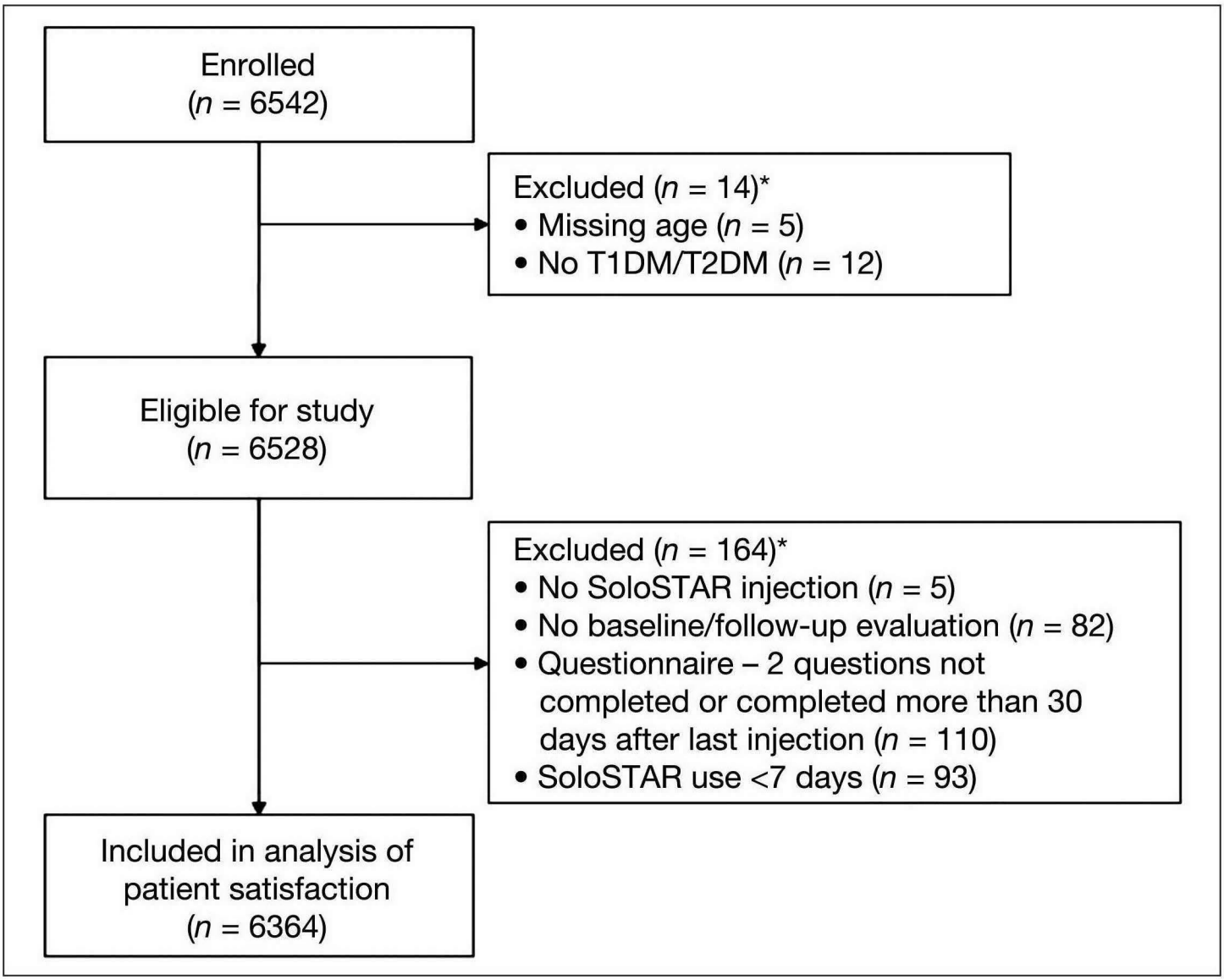

Figure 1. Participant disposition. The safety population (*n* = 6481) included all eligible patients excluding those who did not inject SoloSTAR (*n* = 47). *Patients may have more than one reason for exclusion.

follow-up questionnaire was missing or completed more than 30 days after the last injection (n = 110; patients were allowed more than one reason for exclusion). The characteristics of the eligible patients are shown in **Table 1**.

Most patients (77.1%) had previously received insulin (**Table 1**), and the majority were using basal or rapid-acting insulin, with similar proportions of patients using analog or human insulins; doses of insulin prior to the study are presented in **Table 1**. The majority of patients

Table 1.
Baseline Characteristics and Prior Insulin Therapy[a]

Characteristic	T1DM	T2DM	Total population
N	1817	4664	6481
Age (years)	40.4 ± 13.8	59.7 ± 10.6	54.3 ± 14.5
18–35	715 (39.4)	65 (1.4)	780 (12.0)
35–60	939 (51.7)	2458 (52.7)	3397 (52.4)
60–70	136 (7.5)	1383 (29.7)	1519 (23.4)
70–80	22 (1.2)	656 (14.1)	678 (10.5)
>80	5 (0.3)	102 (2.2)	107 (1.7)
Sex			
Male	948 (52.2)	2209 (47.4)	3157 (48.7)
Female	869 (47.8)	2455 (52.6)	3324 (51.3)
Weight (kg)	73.8 ± 15.2	86.8 ± 17.4	83.1 ± 17.8
Height (cm)	171.0 ± 9.4	168.4 ± 9.0	169.1 ± 9.2
Body mass index (kg/m^2)	25.2 ± 4.5	30.6 ± 5.6	29.1 ± 5.9
<25	1014 (56.2)	677 (14.7)	1691 (26.3)
25–30	570 (31.6)	1673 (36.2)	2243 (34.9)
≥30	219 (12.1)	2270 (49.1)	2489 (38.8)
Prior insulin therapy			
Yes	1736 (95.5)	3259 (69.9)	4995 (77.1)
Prior analog insulin (U)			
Basal insulin	26 ± 13 (n = 909)	36 ± 23 (n = 1160)	31 ± 20 (n = 2069)
Rapid-acting insulin	29 ± 13 (n = 1113)	37 ± 21 (n = 952)	33 ± 17 (n = 2065)
Premixed insulin	40 ± 21 (n = 79)	53 ± 31 (n = 291)	50 ± 30 (n = 370)
Prior human insulin (U)			
Basal insulin	25 ± 13 (n = 671)	30 ± 19 (n = 1412)	29 ± 17 (n = 2083)
Rapid-acting insulin	29 ± 15 (n = 493)	37 ± 19 (n = 933)	34 ± 18 (n = 1426)
Premixed insulin	33 ± 16 (n = 93)	47 ± 23 (n = 279)	43 ± 22 (n = 372)
Use of an insulin pen before inclusion[b]			
Yes	1717 (98.9)	3092 (94.9)	4809 (96.3)
Prefilled	538 (31.0)	1103 (33.8)	1641 (32.9)
Reusable	1313 (75.6)	2082 (63.9)	3395 (68.0)
LANTUS SoloSTAR	337 (19.3)	1491 (32.9)	1828 (29.2)
Apidra SoloSTAR	547 (38.1)	1382 (35.2)	1929 (36.0)

[a] Values are mean ± SD or n (%).
[b] Only patients using insulin before inclusion.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.