

Patient Satisfaction and Glycemic Control After 1 Year With Inhaled Insulin (Exubera) in Patients With Type 1 or Type 2 Diabetes

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OBJECTIVE — The aim of this study was to determine patient satisfaction in patients with type 1 or type 2 diabetes receiving an inhaled insulin or subcutaneous insulin regimen, as assessed by pooled analysis of two 12-week parent studies and 1-year extension studies.

RESEARCH DESIGN AND METHODS — In the 12-week parent studies, patients with type 1 ($n = 70$) or type 2 ($n = 51$) diabetes were randomized to an inhaled insulin or subcutaneous insulin regimen. In the 1-year extension studies, patients were allowed to select either treatment regimen. Patient satisfaction was assessed at baseline, week 12, and 1 year using the Patient Satisfaction with Insulin Therapy questionnaire.

RESULTS — Of the 60 patients who received inhaled insulin during the parent studies, 85.0% ($n = 51$) chose to continue treatment, 13.3% ($n = 8$) switched to subcutaneous insulin, and 1.7% ($n = 1$) did not continue. Of the 61 patients who received subcutaneous insulin, 21.3% ($n = 13$) chose to continue treatment, 75.4% ($n = 46$) switched to inhaled insulin, and 3.3% ($n = 2$) did not continue. From baseline (parent studies) to 1 year (extension studies), HbA_{1c} reductions of 0.8% were sustained, and greater improvements were observed in the inhaled insulin group compared with the subcutaneous insulin group in terms of overall satisfaction (37.9 vs. 3.1%; $P < 0.01$) and ease of use (43.2 vs. -0.9%; $P < 0.01$).

CONCLUSIONS — Inhaled insulin was preferred over subcutaneous insulin, which resulted in greater patient satisfaction up to 1 year in patients with type 1 or type 2 diabetes with durable effects on HbA_{1c} levels.

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Long-term prospective studies have demonstrated the benefits of long-term glycemic control in reducing the risk of secondary complications in people with type 1 or type 2 diabetes (1–4).

Individuals with type 2 diabetes

might have a positive attitude toward insulin in terms of efficacy, prevention of complications, and improved well-being (1). However, this might be offset by practical problems of insulin administration, such as fear of needles, technique, and general inconvenience (5). Therefore, in-

ulin use may be postponed for years and reserved as a last resort after the traditional stepwise approach of diet, exercise, and glucose-lowering agents has failed to produce and maintain adequate glycemic control.

Advances in insulin delivery, however, may lead to increased patient and physician satisfaction and more favorable outcomes. The clinical development of a novel, noninvasive, pulmonary dry-powder insulin delivery system (Exubera) (being developed by Pfizer and Aventis Pharmaceuticals in conjunction with Nektar Therapeutics) shows promise as an effective, well-tolerated therapy for type 1 and type 2 diabetes.

Two 12-week clinical studies demonstrate the efficacy of inhaled insulin in patients with type 1 or type 2 diabetes (6–8). In addition, these studies show that increased patient satisfaction is obtained with an inhaled insulin regimen compared with a subcutaneous insulin regimen (8,9). Data indicate that improvements in patient satisfaction are consistently correlated with improvements in glycemic control, raising the likelihood of increased treatment compliance. We report the 1-year results of patient satisfaction and preference as well as effects on HbA_{1c} levels with inhaled insulin (Exubera) compared with a subcutaneous insulin regimen in patients with type 1 or type 2 diabetes.

RESEARCH DESIGN AND METHODS

Two short-term (12-week) parent studies were carried out: subjects with type 1 diabetes (study 1) and subjects with type 2 diabetes (study 2). For inclusion in the studies, men or women aged 18–55 years (type 1) or 35–65 years (type 2) had to meet the following entry criteria: prerandomization HbA_{1c} of 7–12%; fasting plasma C-peptide ≤ 0.2 ng/ml (≤ 0.07 pmol/ml) (type 1) or ≥ 0.6 ng/ml (≥ 0.2 pmol/ml) (type 2); body weight 80–130% (type 1)

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Abbreviations: PSIT, patient satisfaction with insulin therapy.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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or 100–175% (type 2) of ideal; and a normal chest X-ray and pulmonary function (forced expiratory volume in 1 s, forced vital capacity, and carbon monoxide diffusing capacity $\geq 80\%$ of predicted; total lung capacity 80–120% of predicted). Subjects were excluded if they had major organ system disease, a history of epilepsy, asthma, or other respiratory diseases, two or more serious hypoglycemic episodes within the previous year, or were smokers (any smoking within the previous 6 months).

Efficacy and tolerability of inhaled insulin were assessed in two 12-week, open-label studies involving subjects with type 1 or type 2 diabetes (6–8). Following a 4-week lead-in period during which subjects received their usual subcutaneous insulin regimen of two to three injections per day, subjects were randomized to an inhaled insulin regimen (pre-meal inhaled insulin plus a single bedtime subcutaneous injection of Ultralente insulin) or a subcutaneous insulin regimen (conventional regimen of two to three subcutaneous injections per day, based on the subject's usual split/mixed insulin regimen). Subjects received instruction on a weight-maintaining diet and blood glucose monitoring. Glucose monitoring instructions for both treatment groups called for finger-stick measurements a minimum of four times daily: before breakfast, lunch, supper, and bedtime. Insulin administration (inhaled or injected) was to be preceded by a blood glucose check. Identical target glucose levels were established for both groups, and insulin dosage was adjusted on a weekly basis if target levels were not achieved.

Subjects who successfully completed the 12-week parent studies were given the option to continue long-term open-label therapy and could choose either treatment regimen (inhaled insulin or subcutaneous insulin) for the 1-year extension studies regardless of the treatment used in the parent study. Each center's institutional review board approved the protocol, and all subjects gave written informed consent for the studies.

Treatment administration

Pre-meal inhaled insulin was delivered in one to two inhalations. Dry-powder insulin was packaged in blister packs of 1- and 3-mg doses, the equivalent of ~ 3 and 9 IU of subcutaneous insulin, respectively. During the extension studies, inhaled in-

sulin was dosed before meals; the principal investigator individualized all other diabetes therapies.

Assessments

HbA_{1c} and pulmonary function tests (spirometry, lung volume, and single-breath carbon monoxide diffusing capacity) were assessed every 3 months in the extension studies. The occurrence of a hypoglycemic episode was recorded if any of the following criteria were met: 1) a typical clinical picture in the absence of a blood glucose check but with prompt resolution on food intake; 2) a typical clinical picture with a blood glucose check confirming blood glucose < 60 mg/dl; and/or 3) any recorded blood glucose < 50 mg/dl. A "severe" hypoglycemic episode was defined as one requiring the assistance of another person or involving seizures or coma. All other episodes were graded as "mild to moderate."

Patient satisfaction was a secondary efficacy outcome. It was assessed using the Patient Satisfaction with Insulin Therapy (PSIT) questionnaire, which has undergone rigorous empirical development and a series of successful validations (8–10). The PSIT questionnaire has one total score that measures global (overall) satisfaction and two subscale (domain) scores: one subscale score on convenience/ease of use and another subscale score on social comfort. The PSIT questionnaire is shown in Cappelleri et al. (8,10) and Gerber et al. (9).

Statistical analysis

Descriptive statistics were obtained for clinical and safety measures. For the PSIT questionnaire, responses to each satisfaction item were analyzed with a higher score indicating greater satisfaction. All 15-item scores were summed equally to arrive at scores for overall satisfaction (15 items, range 15–75), ease of use (10 items, range 10–50), and social comfort (5 items, range 5–25). Data from both studies were pooled. Mean percentage changes in satisfaction with treatment regimens were assessed from the baseline visit (parent studies) to the 12-week visit (parent studies) and also to around the 1-year visit in the extension studies. Changes in satisfaction between and within treatment regimens were calculated using linear regression models that adjusted for the following covariates of interest: duration of diabetes, sex, race,

age, and study, as well as changes in HbA_{1c}, BMI, and fasting plasma glucose.

RESULTS— Baseline characteristics of patients in the parent studies are listed in Table 1.

Clinical outcomes

Glycemic control. At the end of the 12-week parent studies, the adjusted mean differences between changes in HbA_{1c} were similar for both treatment regimens in patients with type 1 diabetes (inhaled -0.69% ; subcutaneous -0.85% ; treatment group difference 0.16 [95% CI -0.2 to 0.5]) and type 2 diabetes (inhaled -0.61% ; subcutaneous -0.79% ; treatment group difference 0.18 [95% CI -0.2 to 0.6]) after adjusting for baseline HbA_{1c} and study center.

Of 118 subjects, 102 completed the 1-year extension. No discernable differences were seen between dropouts and completers except mean age (36.4 vs. 44.9 years; $P < 0.01$) and duration of diabetes (9.2 vs. 13.8 years; $P = 0.03$).

Mean changes in efficacy and safety variables from baseline (parent studies) to the 1-year visit (extension studies) are shown in Table 2. Descriptive analyses at the end of the 1-year extension show that HbA_{1c} mean \pm SD changes were: $-0.78 \pm 0.87\%$ (inhaled \rightarrow inhaled, $n = 44$); $-0.72 \pm 0.71\%$ (subcutaneous \rightarrow inhaled, $n = 39$); $-1.06 \pm 1.09\%$ (subcutaneous \rightarrow subcutaneous, $n = 13$); and $-0.37 \pm 0.75\%$ (inhaled \rightarrow subcutaneous, $n = 6$).

In subjects with at least 12 months' exposure to inhaled insulin, hypoglycemic event rates were stable during the year of observation (crude event rates 3.11 events/subject-month during the first 3 months; 2.75 events/subject-month during the 3- to 6-month period; and 2.52 events/subject-month during the 6- to 12-month period). Changes in weight were comparable between treatment groups.

Safety and tolerability. In the parent studies, mean changes in pulmonary function tests were small and comparable between the two treatment groups (6–8). During the 1-year extension studies, changes in pulmonary function in patients who received inhaled insulin were also small and comparable with those patients receiving subcutaneous insulin.

Table 1—Baseline demographic and clinical characteristics

	Inhaled insulin	Subcutaneous insulin
Patients with type 1 diabetes		
<i>n</i>	35	35
Sex (male/female)	19/16	18/17
Age (years)	35.4 ± 9.0	39.8 ± 8.7
Duration of diabetes (years)	14.6 ± 9.3	14.2 ± 9.4
Race/ethnic group		
White	29 (83)	27 (77)
Black	1 (3)	1 (3)
Hispanic	0 (0)	1 (3)
Other	5 (14)	6 (17)
Weight		
Men (kg)	81.1 ± 11.3	82.2 ± 10.8
Women (kg)	64.6 ± 7.0	64.8 ± 8.6
BMI		
Men (kg/m ²)	25.1 ± 2.7	26.0 ± 2.6
Women (kg/m ²)	24.4 ± 2.3	24.7 ± 3.4
Baseline HbA _{1c} (%)	8.5 ± 1.2	8.5 ± 1.1
Satisfaction scores		
Global	52.9 ± 12.9	52.7 ± 11.2
Ease of use	35.4 ± 8.7	35.4 ± 9.1
Social comfort	17.5 ± 5.5	17.3 ± 4.9
Patients with type 2 diabetes		
<i>n</i>	25	26
Sex (male/female)	15/10	15/11
Age (years)	50.6 ± 8.1	52.9 ± 7.5
Duration of diabetes (years)	11.2 ± 7.7	11.5 ± 6.5
Race/ethnic group		
White	10 (40)	16 (62)
Black	4 (16)	3 (12)
Other	11 (44)	7 (27)
Weight		
Men (kg)	95.0 ± 17.4	90.1 ± 15.8
Women (kg)	80.4 ± 11.6	83.9 ± 9.2
BMI		
Men (kg/m ²)	29.9 ± 4.1	28.3 ± 3.8
Women (kg/m ²)	33.1 ± 4.9	32.8 ± 3.8
Baseline HbA _{1c} (%)*	8.7 ± 1.4	7.9 ± 0.9
Satisfaction scores		
Global	50.5 ± 11.6	54.9 ± 9.7
Ease of use	35.3 ± 8.4	38.2 ± 8.3
Social comfort	15.3 ± 5.1	16.8 ± 3.1

Data are means ± SD or *n* (%). **P* < 0.05 for mean difference between regimens.

Patient-reported outcomes

Treatment preference. At the end of the two 12-week parent studies, 60 patients randomized to inhaled insulin and 61 patients randomized to subcutaneous insulin were eligible for participation in the extension studies. Of the 60 patients receiving inhaled insulin in the parent studies, 51 (85.0%) chose to continue treatment, 8 (13.3%) switched to subcutaneous insulin, and 1 (1.7%) did not

continue. Of the 61 patients on subcutaneous insulin, 13 (21.3%) chose to continue the same insulin treatment, 46 (75.4%) switched to inhaled insulin, and 2 (3.3%) did not continue.

In total, 75.4% of patients switched from subcutaneous insulin to inhaled insulin, and 13.3% switched from inhaled insulin to subcutaneous insulin (McNemar test, *P* < 0.0001). Significantly more patients randomized to inhaled insulin

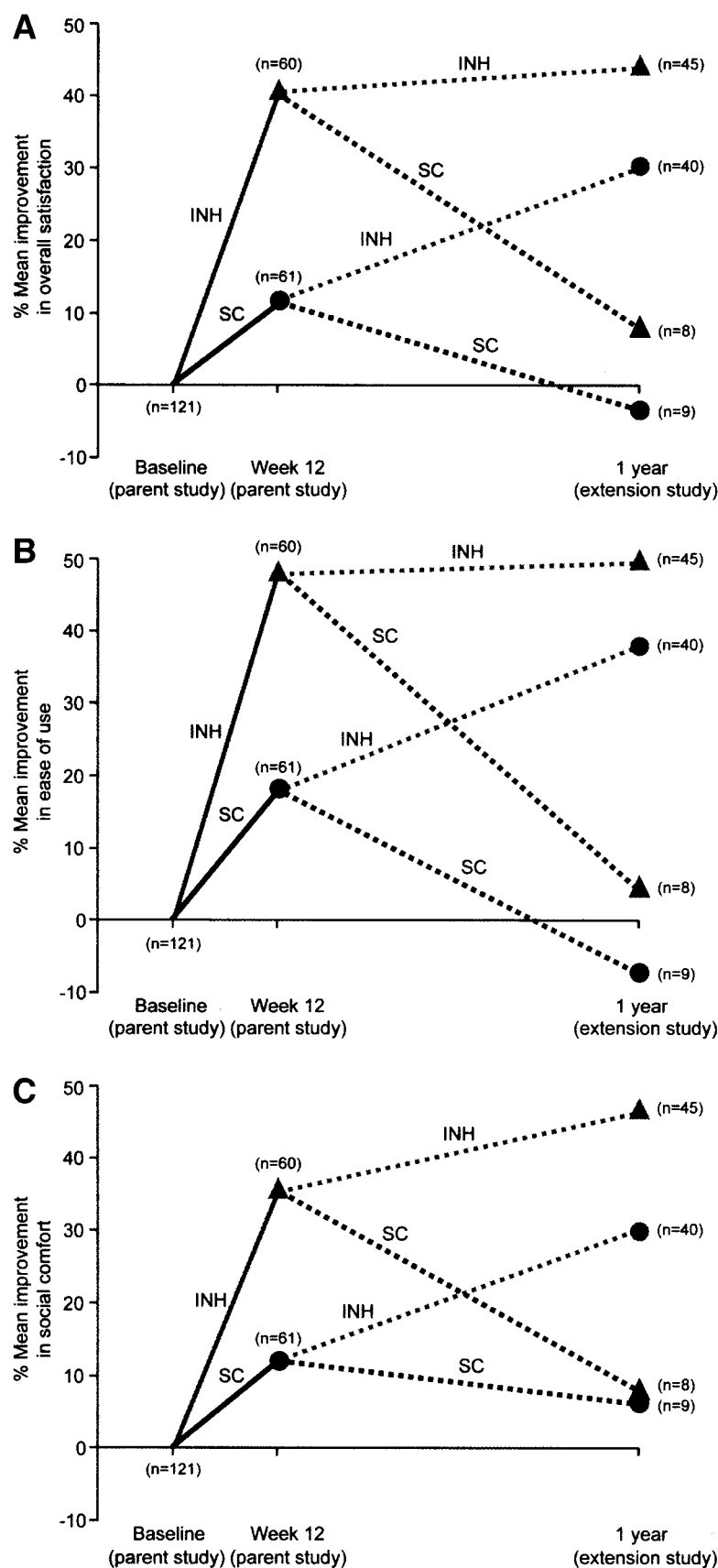
agreed with the statement “I would like to continue to take insulin the way I took it during the study” compared with those in the subcutaneous insulin regimen at the end of the 12-week parent studies (Wilcoxon’s rank-sum test, *P* < 0.01).

Patient satisfaction: between-group analysis. Of the 121 patients eligible for the extension studies, 113 completed the entire PSIT questionnaire, and 107 had a complete set of relevant covariates at the end of the 12-week parent studies. At the end of the 1-year extension studies, 109 completed the entire PSIT questionnaire, and 102 had a complete set of relevant covariates. Of the 102 subjects, 85 were randomized in the parent study to either inhaled insulin (*n* = 45) or subcutaneous insulin (*n* = 40) and chose inhaled insulin in the extension study (inhaled → inhaled, *n* = 45; subcutaneous → inhaled, *n* = 40). The remaining 17 patients were randomized in the parent study to either inhaled (*n* = 8) or subcutaneous (*n* = 9) insulin and chose subcutaneous insulin in the extension studies (inhaled → subcutaneous, *n* = 8; subcutaneous → subcutaneous, *n* = 9).

From the baseline visit in the 12-week parent studies to the 1-year visit in the extension studies, greater improvements were observed with inhaled insulin compared with subcutaneous insulin in overall satisfaction (37.9 vs. 3.1%; *P* < 0.01) and ease of use (43.2 vs. -0.9%; *P* < 0.01). Estimates of social comfort favored inhaled insulin compared with subcutaneous insulin (39.3 vs. 8.7%; *P* = 0.11). Similar results were also observed from baseline to week 12 of the parent studies.

Patient satisfaction: within-cohort analysis. Figure 1 provides a longitudinal descriptive profile of each within-treatment cohort. This figure depicts within-treatment cohort changes in satisfaction scores from baseline to week 12. Also shown are within-treatment cohort changes in satisfaction scores from baseline visit in the 12-week parent studies to 1 year in the extension studies for four cohorts (inhaled → inhaled; subcutaneous → inhaled; subcutaneous → subcutaneous; inhaled → subcutaneous), allowing for descriptive comparisons with changes from baseline to week 12 (parent studies).

As shown in Fig. 1A, patients randomized to inhaled insulin in the parent studies who continued on inhaled insulin in the extension studies (*n* = 45) had



maintained their overall satisfaction. Patients randomized to inhaled insulin in the parent studies who switched to subcutaneous insulin in the extension studies ($n = 8$) showed a marked decrease in level of overall satisfaction. Patients randomized to subcutaneous insulin in the parent studies who continued on subcutaneous insulin in the extension studies ($n = 9$) had an incremental decrease in overall satisfaction. Similar trends were observed with ease of use and social comfort (Fig. 1B and C, respectively). Moreover, patients randomized to subcutaneous insulin in the parent studies who then switched to inhaled insulin in the extension studies ($n = 40$) showed statistically significant improvements from baseline in the parent studies to 1 year in the extension studies in overall satisfaction (29.9%; $P = 0.0007$), ease of use (37.8%; $P = 0.0001$), and social comfort (30.3%; $P = 0.04$).

CONCLUSIONS— Results of short-term (12-week) studies indicate that glycemic control achieved with an inhaled insulin regimen is comparable with a subcutaneous insulin regimen in patients with type 1 diabetes (7) and type 2 diabetes (6,8). These studies also showed greater patient satisfaction with inhaled insulin compared with subcutaneous insulin as well as an association between glycemic control and patient satisfaction with treatment (8–10).

Similarly, results of phase III studies have shown that reducing the number of injections through treatment with inhaled insulin greatly enhances patient satisfaction, quality of life, and acceptance of intensive insulin therapy in patients with type 1 or type 2 diabetes (11,12). Moreover, it has been determined in patients with type 1 diabetes that improvement in

Figure 1—Adjusted mean percentage improvement in overall satisfaction (A), ease of use (B), and social comfort (C), including four treatment cohorts from baseline in the parent studies to 1 year in the extension studies. Results are adjusted for duration of diabetes, sex, race, age, and study, as well as for changes in HbA_{1c} , BMI, and fasting plasma glucose. Sample sizes in parent studies from baseline to week 12: $n = 60$, inhaled insulin regimen (INH); $n = 61$, subcutaneous insulin regimen (SC). Sample sizes from baseline in the parent studies to 1 year in the extension studies: INH \rightarrow INH, $n = 45$; INH \rightarrow SC, $n = 8$; SC \rightarrow INH, $n = 40$; SC \rightarrow SC, $n = 9$.

Table 2—Efficacy and safety variables

	Treatment group (parent → extension)			
	Inhaled → inhaled	Subcutaneous → inhaled	Subcutaneous → subcutaneous	Inhaled → subcutaneous
HbA _{1c}	-0.78 ± 0.87	-0.72 ± 0.71	-1.06 ± 1.09	-0.37 ± 0.75
n	44	39	13	6
Forced expiratory volume in 1 s (liters)	-0.03 ± 0.22	-0.05 ± 0.16	0.02 ± 0.35	0.02 ± 0.08
n	44	40	13	6
Diffusion capacity (ml · min ⁻¹ · mmHg ⁻¹)	-1.05 ± 4.69	-2.50 ± 6.95	-2.53 ± 4.82	-1.51 ± 4.68
n	43	39	13	6
Fasting plasma glucose (mg/dl)	-10.05 ± 89.85	-27.63 ± 77.32	-27.54 ± 84.33	-6.83 ± 128.07
n	44	40	13	6
Weight (kg)	-0.24 ± 2.64	1.01 ± 2.73	0.98 ± 1.83	0.59 ± 3.02
n	44	40	13	6

Data are means ± SD change from baseline (prerandomized) visit in the 12-week parent studies to the planned year 1 visit in the extension studies.

overall patient satisfaction with inhaled insulin is rapid and sustainable compared with conventional subcutaneous insulin, and the reduced treatment burden has a positive impact on psychological well-being (13).

In this study, inhaled insulin appeared to be highly acceptable to and preferred by patients with type 1 or type 2 diabetes. Eighty-five percent of patients treated with inhaled insulin during the 12-week parent studies chose to continue treatment during the 1-year extension studies, whereas only 21.3% of patients treated with subcutaneous insulin during the parent studies chose to remain on the regimen. In addition, patients treated with subcutaneous insulin for the first 12 weeks who then switched to inhaled insulin during the nonrandomized extension study ($n = 40$) showed significant improvement in satisfaction relative to baseline. Conversely, patients who chose to return to subcutaneous insulin after inhaled insulin in the parent study ($n = 8$) and patients who chose to continue on subcutaneous insulin after the parent study ($n = 9$) had lower satisfaction at 1 year in the extension study.

Results from the current investigation are the first to suggest that the rapid improvement in patient satisfaction with inhaled insulin is sustained, and long-term improvements in glycemic control and patient satisfaction are maintained up to the 1-year follow-up.

In patients with type 1 or type 2 diabetes, inhaled insulin is preferred over subcutaneous insulin, and this results in improved patient satisfaction in the longer term (1 year) as well as in the short

term (12 weeks). Inhaled insulin may offer a noninvasive management option that can help maintain long-term glycemic control comparable with subcutaneous insulin while significantly improving patient satisfaction.

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