Overall satisfaction increased more with inhaled insulin than with subcutaneous insulin in type 1 diabetes

QUESTION

In patients with type 1 diabetes mellitus, is patient satisfaction greater with inhaled insulin use than with subcutaneous insulin injection?

DESIGN

Randomized {allocation concealed*}†, unblinded,* controlled trial with 12-week follow-up.

SETTING

10 centers in the United States.

PATIENTS

{72 patients}‡ who were 18 to 55 years of age and were following a stable insulin administration schedule of 2 to 3 daily injections for ≥ 2 months. Other inclusion criteria were screening and prerandomization glycosylated hemoglobin values between 7.0% and 11.9%, fasting plasma C-peptide level ≤ 0.2 pmol/mL, body weight 80% to 130% of ideal, nonsmoking for ≥ 6 months, normal results on chest x-ray and pulmonary function tests, and normal sinus rhythm (rate 50 to 100 beats/min). 69 patients (96%) (mean age 37 y, 54% men, 80% white) were considered for analysis.

INTERVENTION

35 patients were allocated to receive preprandial inhaled insulin immediately before meals using a dry-powder aerosol delivery system and subcutaneous ultralente insulin at bedtime. 37 patients were allocated to receive subcutaneous insulin (control group) 2 or 3 times/d according to each patient's usual split or mixed insulin regimen.

MAIN OUTCOME MEASURES

A self-administered questionnaire (Patient Satisfaction with Insulin Therapy) developed by Pfizer Inc. was used to measure overall satisfaction (score range 15 to 75), convenience or ease of use (score range 10 to 50), and social comfort (score range 5 to 25).

MAIN RESULTS

{Analysis was by intention to treat}†. Patients who completed all items in the overall scale or in each subscale of the questionnaire at baseline and at 12 weeks were included in the analysis (range 92% to 94%). At 12 weeks, patients in the inhaled-insulin group had greater increases in overall satisfaction and convenience or ease-of-use scores than did those in the subcutaneous-insulin group (Table). Groups did not differ for increase in social comfort (Table).

CONCLUSION

In patients with type 1 diabetes mellitus, increases in overall satisfaction and convenience or ease of use were greater with inhaled insulin than with subcutaneous insulin injection, but groups did not differ for increase in social comfort.

Inhaled vs subcutaneous insulin in type 1 diabetes at 12 weeks§

Outcomes	Mean percentage increase from baseline		Difference (95% CI)
	Inhaled	Subcutaneous	
Overall satisfaction	35%	11%	25% (6.6 to 43)
Convenience or ease of use	41%	11%	30% (11 to 50)
Social comfort	28%	18%	10% (−15 to 35)

§Outcomes measured with Patient Satisfaction with Insulin Therapy Questionnaire; higher score = greater satisfaction.
‖Calculated from data in article.

COMMENTARY

The core finding in the study by Gerber and colleagues was a greater improvement in overall satisfaction among patients receiving inhaled plus 1 subcutaneous injection of insulin than among those continuing 2 or 3 daily injections of insulin. Details of the insulin regimens are sparse, but patients received a mixture of short and medium-acting conventional insulins. Whether these were premixed preparations or how they were administered is not clear. These questions are not trivial because many patients with type 1 diabetes find it inconvenient to draw up 2 different insulins into the same syringe. Moreover, once a medium-acting preparation is injected at breakfast, the patient is committed to consuming a meal several hours later. Current advice is that conventional, short-acting insulins be given 20 to 30 minutes before eating. Finally, many patients report that insulin pens and their needles are much more portable and less painful than disposable syringes.

Comparing inhaled insulin that is given immediately before meals and uses a new technology (a new therapy that interested patients enough to enroll in a study) with a less convenient regimen was likely to result in greater satisfaction. What is surprising is the almost 11% overall increase in satisfaction in those continuing subcutaneous injections. However, this study was not large enough to show differences in social comfort in users of the bulky insulin inhaler, but the beneficial trend is consistent with a previous study (1).

Other problems exist with inhaled insulin. In dose-equivalence terms, 10 times more insulin needs to be given before meals with the inhaler than with injection. Short-term respiratory function reported in this study did not change, and preliminary data suggest no detectable problems at 24 months (2). However, longer-term surveillance is essential.

To appropriately test the hypothesis that inhaled insulin is more acceptable to patients, a crossover trial comparing it with multiple injection therapy using fast-acting analogues in patients with good glycemic control (perhaps < 8% glycosylated hemoglobin value) needs to be done.

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References
1. **Cappelleri JC, Gerber RA, Rosenstock J, et al.** Diabetes. 2001;50(Suppl 2):A108.
2. **Cefalu WT.** Ann Intern Med. 2001;134:795.