Intuitiveness, Instruction Time, and Patient Acceptance of a Prefilled Insulin Delivery Device and a Reusable Insulin Delivery Device in a Randomized, Open-Label, Crossover Handling Study in Patients with Type 2 Diabetes

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ABSTRACT

Background: Because the use of insulin therapy can place a substantial burden on patients with diabetes, insulin administration should be as simple as possible.

Objectives: The primary aim of this trial was to compare the use of 2 insulin delivery devices—one prefilled (NovoMix® 30 FlexPen® [FP]; Novo Nordisk, Copenhagen, Denmark) and the other reusable (HumaPen® Luxura™ [HL]; Eli Lilly and Company, Indianapolis, Indiana)—in patients with type 2 diabetes in terms of intuitiveness and training time. A secondary aim was to evaluate the ease of use and overall acceptance of the 2 devices.

Methods: This was a randomized, open-label, comparative, crossover handling study in adult patients with type 2 diabetes who had been treated with oral antidiabetic drugs for ≥2 years and had no previous experience with insulin injection devices. Patients were randomly allocated to the intuitiveness group (no instruction in the use of the devices provided) or the instruction group (instruction provided). The time taken to deliver an injection into a cushion was measured for each device in both groups. Patients answered questionnaires concerning the intuitiveness and ease of use of the 2 devices, their trust and confidence in the devices to deliver the insulin dose, and their overall pen preference.

Results: Sixty-one patients were enrolled in the study (70.5% male; mean [SD] age, 61.80 [7.60] years), 30 in the intuitiveness group and 31 in the instruction group. When all handling steps for the HL device were included, the mean (SD) injection time was significantly shorter for the FP device compared with the HL device in the intuitiveness group (1.21 [1.04] vs 1.74 [0.79] minutes, respectively; $P = 0.035$). The outcome was similar in the instruction group (0.71 [0.29] vs 1.09 [0.49] minutes; $P < 0.001$). When the time for cartridge insertion in the HL device was excluded, there was no significant difference in injection time for the respective devices in either group (intuitiveness group: 1.21 [1.04] and 1.07 [0.91] minutes; instruction group: 0.63 [0.35] and 0.71 [0.29] minutes). Twenty-two patients preferred the FP device in terms of ease of learning, compared with 8 patients preferring the HL device ($P = 0.007$).

Conclusions: In this study, when all handling steps were included, the FP device was associated with significantly greater intuitiveness and a shorter injection time compared with the HL device. Further research is needed to determine whether these differences between devices are clinically meaningful. (*Clin Ther.* 2008;30:2252–2262) © 2008 Excerpta Medica Inc.

Key words: insulin pen, FlexPen®, HumaPen® Luxura™, type 2 diabetes, handling test.

INTRODUCTION

Insulin is considered the gold standard of diabetes treatment, essential in patients with type 1 diabetes and desirable in patients with type 2 diabetes (particularly as the disease progresses). However, because intensive insulin therapy consisting of ≥3 insulin injections daily places a substantial burden on patients, insulin administration should be as simple as possible.[1]

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The availability of pen devices has simplified the administration of insulin for patients, particularly compared with the traditional vial and syringe.[2] A multicenter, randomized, open-label, 2-period crossover trial in patients with type 1 or 2 diabetes compared patients' preference for a prefilled disposable insulin pen or a conventional vial/syringe.[2] Of 103 patients who completed the study, 74% indicated a preference for the pen and 20% a preference for the vial/syringe. The pen was considered more discreet for use in public by 85% of patients, compared with 9% who considered the vial/syringe more discreet.

Administration by pen is recognized as being more accurate than administration by syringe in terms of insulin dose and delivery, particularly at lower doses (<5 IU).[3] The accuracy of insulin dosing is important in terms of maintenance of glycemic control. If patients are not able to trust their device to deliver the correct required insulin dose, they may lose confidence in treatment and become less adherent. Two recent studies tested the dosing accuracy (measured as weight of insulin discharged at set doses) of different insulin pens. One study found the FlexPen® (Novo Nordisk, Copenhagen, Denmark) to be more accurate than the SoloStar® device (Sanofi-Aventis, Paris, France) at delivering doses of 5, 10, and 30 IU.[4] The other study reported that the FlexPen and HumaPen® Luxura™ (Eli Lilly and Company, Indianapolis, Indiana)—hereafter referred to as *HL*—were more accurate than the OptiClik® (Sanofi-Aventis) and SoloStar devices at delivering doses of 10 and 30 IU.[5]

Despite an apparent preference for the ease of use of an insulin pen device, patients with type 2 diabetes may be reluctant to consider subcutaneous insulin treatment.[6] They may be concerned about preparation of the correct insulin dose, may lack confidence in their ability to deliver accurate doses of insulin, may be embarrassed about administering injections in public, or may fear the injection itself.[1] Factors such as these may limit patients' overall confidence in self-managing diabetes with insulin. Thus, devices that are intuitive and easy to learn, and that encourage confidence and trust may help patients overcome concerns regarding the administration of insulin.[1]

In addition, health care providers may be unwilling to initiate insulin therapy in patients with type 2 diabetes. Lack of instruction time has been cited by physicians as a reason for delaying the initiation of insulin therapy.[1] Therefore, the need for minimal training in the use of pen devices is desirable from the point of view of a health care professional guiding patients with no previous experience in the use of insulin delivery devices.

Several insulin pen devices are available, each with distinct features, making it important to evaluate devices with specific patient needs in mind.[7] The NovoMix® 30 FlexPen® (Novo Nordisk)—hereafter referred to as *FP*—is a disposable, prefilled insulin pen that has a delivery range of 1 to 60 U, with dosing increments of 1 U and a total insulin volume of 3 mL. The HL device is a reusable insulin pen that has a delivery range of 1 to 30 U, with dosing increments of 0.5 U and a total insulin volume of 3 mL. Although prefilled and reusable pens are different from a technical standpoint, their purpose is the same, and health care professionals and patients are often faced with choosing insulin delivery by one or the other type of device.

The primary aim of this trial was to compare the use of the prefilled FP device and the reusable HL device in patients with type 2 diabetes in terms of intuitiveness (no instruction in the use of the devices provided) and training time (instruction provided). A secondary aim was to evaluate the ease of use and overall acceptance of the 2 devices.

PATIENTS AND METHODS

Patients

Patients were recruited through the Institute for Clinical Research and Development patient referral network, which includes mainly general practitioners and diabetologists. Eligible patients were aged >18 years, had been treated with oral antidiabetic drugs for ≥2 years, and had no previous experience with insulin injection devices. Patients were excluded if they could not read type the size of newspaper body text, were mentally or physically incapacitated, or had neuropathy, visual impairment, or motor disability that would preclude their participation in the study.

Written informed consent was obtained from each patient before study participation. Patients received a small payment to cover their travel costs and time.

Study Design and Procedures

This was a randomized, open-label, comparative, crossover handling study. A computer-generated randomization list was used to allocate patients to group 1 (the intuitiveness group) or group 2 (the instruction