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Preference and resource utilization in elderly patients: InnoLet® versus vial/syringe

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Abstract

InnoLet® is a disposable insulin injection device with a large easy-to-read dial, large push button for injection, and audible clicks for each unit injected. This clinical trial assessed patient preference, satisfaction, and utilization of healthcare resources (estimated nursing care) for InnoLet and vial/syringe. Patients with diabetes mellitus ($N = 79$, mean age 68.2 ± 8.6 years, duration of diabetes 16.5 ± 10.9 years) having visual and/or motor disabilities and having difficulty (or required caregiver assistance) for previous injections by vial/syringe were randomized to use of either InnoLet or vial/syringe for 6 weeks, then switched to the alternate regimen for 6 weeks. At the end of the study, utilization of healthcare resources was assessed in terms of the caregiver time required to assist in preparation, storage, and disposal of each device. For vial/syringe, 60% of patients required assistance in drawing up the appropriate dosage in the syringe, and 36% of patients required assistance when injecting insulin. A major portion of the patients (53%) could independently conduct injections (without nursing/caregiver assistance) during use of InnoLet, versus 20% for vial/syringe. As a result, mean daily nursing costs associated with the injection regimen were US$ 114 for the InnoLet device, and US$ 196 for vial/syringe ($P < 0.001$). A majority of patients (82%) indicated a preference for the InnoLet device ($P < 0.001$).

Keywords: Insulin delivery systems; Healthcare costs; Quality of life; Patient independence; Patient acceptance

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1. Introduction

The Diabetes Control and Complications Trial demonstrated that intensive insulin therapy can significantly reduce the incidence of late diabetic complications, and delay the progression of existing conditions in type 1 diabetes [1]. The United Kingdom Prospective Diabetes Study reported similar findings, and concluded that intensive therapy reduces the risk of many complications of type 2 diabetes (retinopathy, nephropathy, and neuropathy) [2]. Significant costs are accrued by patients with diabetes who have poor glycemic control with insulin [3]. Diabetes is associated with blindness and end stage renal disease. Coronary artery disease is more severe in patients with diabetes.

Many patients with diabetes using insulin injection may have poor treatment compliance. Lack of diabetes education is often a major factor. Other compliance considerations may be poverty, fear of needles, denial, and lifestyle. In elderly patients, diabetes is often complicated by debilitating co-morbidities (vision problems, neuropathy, etc.) that aggravate the difficulties of self-injection and increase the risk of dosing errors. Any treatment approach that allows the patient to more easily self-inject insulin may have implications regarding the financial burden of diabetes complications, deterioration of quality of life, and requirements for nursing assistance.

The InnoLet® insulin injection device was engineered for ease of use. The disposable device has a large, easy-to-read dial, which aids in accurate insulin dose selection by the patient. The large injection button requires less physical effort for a patient with motor impairment (stroke, Parkinson's disease). InnoLet has been previously studied in vision-impaired patients: patients with visual acuities of 20/100 to 20/200 were able to correctly dispense an insulin dose with InnoLet, while 15 and 36% were unable to perform this task with a Humulin pen or vial/syringe, respectively [4].

This study was designed to determine whether the InnoLet injection device provides benefit to elderly patients in terms of nursing resources, treatment satisfaction, and patient preference as compared to the vial/syringe method of insulin injection. Continued quality of care (glycemic control) was also monitored.

2. Methods

2.1. Study design

This trial was performed in accordance with the Declaration of Helsinki, and written informed consent was obtained from all patients. This was a multicenter, randomized, open-label, two-period crossover trial in patients with type 1 or type 2 diabetes mellitus conducted at 11 sites in the United States. The enrolled patients were currently injecting their own insulin (either Novolin N or Novolin 70/30), but had difficulties (requiring some assistance of a nurse or caregiver) due to motor dysfunction (arthritis, familial tremor, Parkinson's disease, stroke-induced partial paralysis) and/or visual problems (partially blind, cataracts, visual field defects, blurred vision). Enrolled patients were familiar with either a pen and/or vial and syringe method of insulin injection. Patients were randomly assigned use of InnoLet with NovoFine® 30G × 8 mm needles or the conventional disposable 0.5 cc Becton-Dickinson insulin syringe with MicroFine 30G permanently attached needle for the first period of 6 weeks in duration, and switched to the alternate device for the second period of 6 weeks. The insulin dose was predetermined based on the patient's prior daily insulin requirements, and was changed over the course of study based on the health needs and/or diet of the patient. In this study, the costs of training patients in the use of InnoLet® were negligible [4].

2.2. Healthcare resource utilization

Healthcare resource utilization for vial/syringe or device use was examined at the end of each study period: a questionnaire was utilized to determine the aspects of use that required assistance (i.e. what percentage of patients required to draw up the appropriate volume, to inject themselves, dispose of the vial/syringe, etc.). For each means of injection, the nursing/caregiver resource utilization was estimated as minutes per day necessary for assisting injection (from injection preparation to disposal): 0 min was indicated if the patient was capable of performing all the activities by themselves. The resource utilization (in dollar amounts) was also calculated in terms of the number of visits per day that nurses/caregivers had to make to the patient in order to assist with insulin injections.

The time necessary for each component (preparation to disposal) was individually tabulated by treatment and study period. If a patient required assistance with any aspect of preparation or injection, they were considered as requiring a nursing visit. Cost calculations were based upon an assumption of $80 per visit (minimum of 1 hr per visit). Comparison of the two devices and the differences in dollar values were made using general linear models for the crossover design.

2.3. Preference and acceptance questionnaires

Patient preference was assessed by a questionnaire at the end of the study: "If you were given the choice of using one of the two systems (vial and syringe or InnoLet), which would you prefer?" Ease of use was also assessed: "Compared with the vial and syringe you were using, injection of insulin with the InnoLet system you are now using is easier, the same or more difficult?" A patient handling and acceptance questionnaire were provided at the end of each 6-week treatment period.

2.4. Efficacy and safety assessments

The glycemic control was assessed by measuring the serum fructosamine levels at the time of screening and at the end of each treatment period. Safety assessments were based on adverse events and adverse device effects, hypoglycemic episodes, vital signs, physical examination and the physicians review of the blood glucose (BG) diaries. Patients recorded meter-measured BG values and symptoms of hypoglycemia associated with blood glucose meter readings.

Hypoglycemia was defined as minor when the patient had a symptom of hypoglycemia (i.e., palpitations, tiredness, sweating, strong hunger, dizziness, tremor, etc.) confirmed by blood glucose meter reading <50 mg/dl, and was able to deal with the episode without assistance. A major or severe hypoglycemic episode was an event that had a blood glucose meter reading <50 mg/dl and required third-party assistance.

2.5. Statistical analysis

For preference data, a two-sided 95% confidence interval was calculated. If the lower limit of the interval was bigger than 50%, the null hypothesis was rejected, and it was concluded that the patients preferred the InnoLet device. A hypothesis of equal treatment median was tested for two treatments, versus the hypothesis that they were not equal. A two-sided test was used when analyzing the comparison. The score data of the questionnaires was not assumed to be a normal distribution; therefore a non-parametric analysis, Wilcoxon Signed Rank test [5] was used for analysis of resource utilization (in dollars), and diabetes treatment satisfaction. A binomial test was used for patient preference.

3. Results

3.1. Demographic and other baseline characteristics

Seventy-nine patients (age 47–85, inclusive) with type 1 or type 2 diabetes and requiring ≤ 50 U of insulin per injection were randomized to the treatment sequence InnoLet $\rightarrow$ vial/syringe or vial/syringe $\rightarrow$ Innolet. A total of 73 (92%) patients out of the 79 completed the study. Five (6%) patients discontinued InnoLet use due to adverse events, non-compliance with protocol, and change of insulin to Lantus. One (1%) patient discontinued use of syringe due to unavailability for follow-up. The demography of randomized patients is summarized in Table 1.

3.2. Insulin regimen

The insulin dose was based upon prior daily insulin requirements, and was changed as necessary over the course of the study. For all patients who completed study treatment, the mean $\pm$ S.E.M. total daily insulin dose at screening was 44.9 ± 0.14 IU/day (range 4–100 IU) for patients using the InnoLet device, and 46.7 ± 0.12 IU/day (range 10–100 IU) for patients using the vial/syringe.

3.3. Healthcare resource utilization (assistance needed)

The resource utilization questionnaire was completed at the end of each trial period. In response to the question "When using a vial and syringe to administer

Table 1
Demographics and baseline characteristics

	Overall
Number randomized, *N*	79
Age (year), mean ± S.D.	68.2 ± 8.6
Sex, *n* (%)	
Male	33 (42)
Female	46 (58)
Race, *n* (%)	
Caucasian	65 (82)
Black	6 (8)
Hispanic	8 (10)
BMI (kg/m^2), mean ± S.D.	33 ± 6.5
A1C (%), mean ± S.D.	7.5 ± 1.4
Years since diagnosis	
Mean ± S.D.	16.5 ± 10.9
Type of diabetes, *n* (%)	
Type 1	2 (3)
Type 2	77 (97)

insulin the patient needs my assistance", 60% of the patients required assistance in drawing up the appropriate volume, and 36% patients required assistance in injecting themselves with insulin. In response to the question "When using a vial and syringe to administer insulin the patient is totally self-sufficient", 25% of patients were self-sufficient (able to prepare, store, and dispose insulin without nursing assistance) using vial/syringe, but using various injection aids (magnifying glass etc.).

3.4. Resource utilization—time in minutes for nursing/caregiver resources

The time (minutes) necessary for assisting injection (from injection preparation to disposal) was assessed by treatment and study period. The mean time spent by nurses or caregivers while assisting in injection preparation was less for patients using the InnoLet device (4.2 ± 8.1 min) than for vial/syringe (5.8 ± 8.9 min).

3.5. Resource utilization—number of visits for nursing/caregiver resources

The resource utilization was tabulated as a percentage of patients requiring/not requiring nursing/caregiver assistance (Table 2). Some patients in the study required as many as three visits per day at US$ 80 per visit. For vial and syringe users, a majority of the patients required such assistance (three daily visits). Only 20% of the patients with vial/syringe reported independence (required no assistance). The mean daily cost was US$ 196 per day for vial/syringe. By comparison, 53% of the patients were independent of nursing/caregiver assistance for injections with InnoLet use, and the mean daily cost of their injections was US$ 114. Overall, the mean daily nursing cost of the InnoLet was significantly less than vial and syringe (US$ 114 versus US$ 196, $P < 0.001$).

3.6. Patient preference, handling, and acceptance of the insulin delivery system

Overall patient preference is summarized in Fig. 1. Patient preference was assessed by the question: "If you were given the choice of using one of the two systems (vial and syringe and InnoLet), which would you prefer?" A majority of patients (82% P-value < 0.001) indicated a preference for the InnoLet device; only 8% indicated no preference in response to this question.

Patient handling and acceptance of the devices was based upon the patient handling and acceptance questionnaire. Patient assessment of their handling experience with InnoLet is summarized in Fig. 2. Patients were asked, "Given your disability, how would you rate the InnoLet compared to vial and syringe: easier

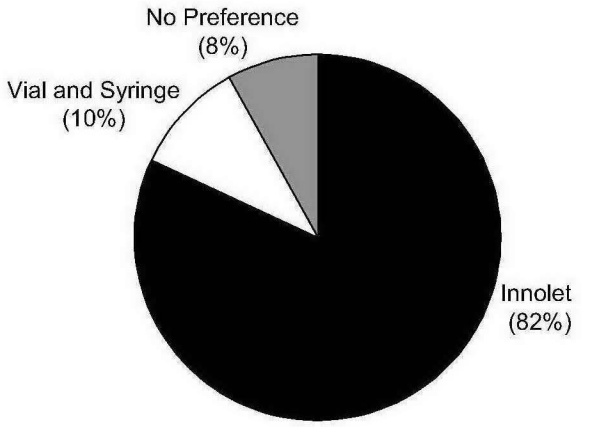

Fig. 1. Overall patient preference: "If you were given the choice of using one of the two systems (vial/syringe and InnoLet), which would you prefer?".

Table 2
Resource utilization: proportion of patients requiring nursing/caregiver assistance

	No. of patients requiring assistance[a] (%)	
	Innolet ($N = 72$)	Vial/syringe ($N = 76$)
Steps of insulin injection		
Store supplies	17 (24)	18 (24)
Prepare individual dosing	16 (22)	46 (61)
Deliver individual dosing	13 (18)	37 (49)
Attach needle to device	15 (21)	N/A
Eliminate air from the needle	9 (13)	33 (43)
Monitor subject's drawing up/dialing up of correct dose	19 (26)	23 (30)
Prepare the site for injection (alcohol swab, pinch skin, etc.)	11 (15)	13 (17)
Insure the patient has dosed themselves properly	16 (22)	13 (17)
Return of supplies to the refrigerator	18 (25)	19 (25)
Dispose of needles (InnoLet)	8 (11)	N/A
Dispose of syringe	N/A	24 (32)
Dispose of vial	N/A	18 (24)
Dispose of InnoLet	17 (24)	N/A
Overall independence		
Patients requiring nursing/caregivers time	34 (47)	61 (80)
Patients not requiring nursing/caregivers time	38 (53)	15 (20)

N/A: not applicable.
[a] Times required for each step were collected. Patients having an estimated caregiver time that did not equal "0" min for that step are tabulated.

to use, the same or harder to use?" A majority of the patients (82%) rated InnoLet easier to use. Only 4% found InnoLet harder to use, whereas 12% found InnoLet and the vial/syringe to be the same.

Patient acceptance of InnoLet is summarized in Fig. 3. Patients were asked: "Just after changing to InnoLet, how did you find managing the practical aspects (dosing and injecting) of the new insulin system?" About 86% of the patients reported that they found "managing the practical aspects" of insulin injection (e.g. dosing and injecting) by InnoLet to be "easy" or "very easy" when initiating insulin treatment, whereas 1% of the patients found the use of InnoLet "difficult" or "very difficult" (Fig. 3A).

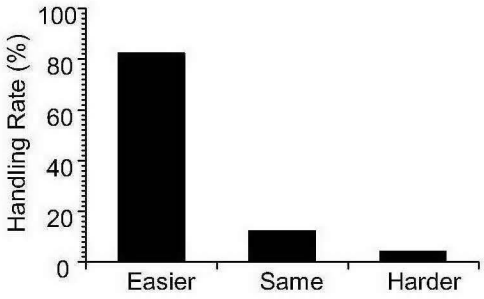

Fig. 2. Patient handling questionnaire. At the end of each study period, patients were asked to complete a patient handling questionnaire. "Given the disability, rate InnoLet compared to vial/syringe." Possible responses: (1) easier to use, (2) the same, and (3) harder to use.

When patients judged the practical aspects of insulin administration after switching to InnoLet, 97% of the patients considered the use of the InnoLet to be "easy" or "very easy," while 3% of the patients found the use of InnoLet to be "difficult" or "a little difficult" to use (Fig. 3B).

When asked about the reliability of insulin injection, 62% rated Innolet as being more reliable than vial/syringe, 34% considered the treatment devices to be "about the same." Only 3% of patients considered InnoLet to be less reliable (Fig. 3C).

Patients were asked: "Were you able to inject yourself with less nursing assistance when using InnoLet?" A majority (84%) of patients indicated that they required less assistance when using InnoLet, 3% required more assistance, and 8% required about the same nursing assistance (Fig. 3D).

Patients showed a positive response to the question: "How did you find the setting of the insulin dose with

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