Preference and resource utilization in elderly patients: InnoLet (R) versus vial/syringe


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The health technology studied was InnoLet with NovoFine 30G x 8mm needles. This consisted of 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 technology was compared with the conventional disposable 0.5cc Becton-Dickinson insulin syringe with MicroFine 30G permanently attached needle.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with type 1 or type 2 diabetes mellitus who were currently injecting their own insulin (either Novolin N or Novolin 70/30), but had difficulties (requiring assistance of a nurse or a 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). Patients were also familiar with either a pen and/or vial and syringe method of insulin injection.

Setting
The setting was primary care. The economic study was carried out in the USA.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not reported. The dates to which the prices related were not stated.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same sample as that used in the effectiveness study.

Study sample
No power calculations to determine the sample size were reported and no specific sample size was determined in the planning phase of this study. Seventy-nine patients, with either type 1 or type 2 diabetes and requiring less than 50 U of insulin per injection, were randomly assigned use of InnoLet or the conventional disposable insulin syringe for the first
period of 6 weeks. They were then switched to the alternative device for the second period of 6 weeks. The study sample consisted of 33 (42%) male patients and 46 (58%) female patients with a mean age (SD) of 68.2 +/- 8.6 years. For those who completed the study treatment, the mean +/- S.E.M. total daily insulin dose at screening was 44.9 +/- 0.14IU/day (range: 4 - 100 IU) for patients using InnoLet, and 46.7 +/- 0.12IU/day (range: 10 - 100 IU) for patients using the vial/syringe.

Study design
The study was a randomised, open-label, two-period crossover trial that was carried out in 11 sites in the United States. The duration of follow-up was 6 weeks for each treatment period. Out of the 79 patients included in the study, a total of 73 (92%) patients 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 method of randomisation was not reported in the paper.

Analysis of effectiveness
It would appear that the analysis of the clinical study was conducted on the basis of treatment completers only. The primary health outcomes used were: time necessary for assisting injection; proportion of patients requiring/not requiring nursing/caregiver assistance; patient preference and ease of use; and glycaemic control. A questionnaire was used to determine the aspects of use that required assistance. Patient preference was assessed by a questionnaire at the end of the study that asked patients the following question: "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 with the following question: "Compared with the vial and syringe you were using, injection of insulin with InnoLet system you are now using is easier, the same or more difficult?" The patient handling and acceptance questionnaires were provided at the end of each 6-week treatment period. Glycaemic 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, hypoglycaemic episodes, vital signs, physical examination and the physicians review of the blood glucose (BG) diaries, where patients recorded meter-measured BG values and symptoms of hypoglycaemia. Hypoglycaemia was defined as minor when the patient had a symptom of hypoglycaemia (i.e. palpitations, tiredness, sweating, strong hunger, dizziness and tremor) confirmed by BG meter reading less than 50mg/dl, and was able to deal with the episode without assistance. A major/severe hypoglycaemia episode was an event that had BG meter reading less than 50mg/dl and required third-party assistance.

Effectiveness results
An 82% majority of patients (p<0.001) indicated a preference for the InnoLet device, with 10% indicating a preference for vial and syringe, and 8% indicating no preference.

A majority of patients (82%) also rated InnoLet easier to use. Only 4% found InnoLet harder to use, and 12% found InnoLet and the vial/syringe to be the same. A further 86% of patients reported that they found 'managing the practical aspects' of insulin injection by InnoLet to be 'easy' or 'very easy' when initiating insulin treatment, whereas 1% found the use of InnoLet 'difficult' or 'very difficult'.

62% of patients 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.

84% of patients indicated that they required less assistance when using InnoLet, 3% required more assistance, and 8% required about the same nursing assistance.

86% of patients reported that they had 'never' drawn an incorrect dose on InnoLet, as opposed to only 10% who sometimes draw an incorrect dose.

73% of patients reported no pain at all when using InnoLet to inject insulin, compared to 26% who found InnoLet slightly painful.

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 minutes) than for vial/syringe (5.8 +/- 8.9 minutes).

34 (47%) patients using InnoLet required nursing/caregivers assistance as opposed to 61 (80%) patients using vial/syringe.

During the treatment of enrolled patients, no change in glycaemic control was observed throughout the entire study period, as measured by fructosamine levels.

Two (3%) patients of 78 using InnoLet reported four serious adverse events and 4 (5%) patients of 76 reported four serious adverse events during vial/syringe treatment. There were no events that were considered by the investigator to be related to the study treatment.

**Clinical conclusions**
The study demonstrated that patients showed a preference for use of the InnoLet insulin injection device over the vial and syringe, with a majority of patients reporting more confidence that the correct amount of insulin was injected using the InnoLet device.

**Measure of benefits used in the economic analysis**
No summary measure of benefit was derived. The study was therefore effectively a cost-consequences analysis.

**Direct costs**
Resource use and costs were reported separately. It is not clear whose direct costs were included in the analysis. The mean daily nursing costs were included in the study, and it is not clear if the authors also included the costs of the insulin injections in the analysis. The authors did not report the source where they obtained the unit costs for the nursing/caregiver visit. The authors assumed that those patients requiring nursing/caregiver assistance would require three visits per day, at US$ 80 per visit. Discounting was not relevant and therefore not performed as all costs were incurred over a very short period. The dates to which the price data refer were not reported. The authors did not include the costs of training patients in the use of InnoLet, as previous studies had shown they were negligible.

**Statistical analysis of costs**
Resource use and costs were treated in a stochastic manner. A non-parametric analysis, Wilcoxon Signed Rank test was used for analysis of resource utilisation (in dollars).

**Indirect Costs**
The indirect costs were not included in the analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The mean daily nursing cost of the InnoLet was significantly less than vial and syringe ($114 versus $196, p<0.001).

**Synthesis of costs and benefits**
The costs and benefits were not combined.

**Authors' conclusions**
The authors concluded that InnoLet could reduce the cost of treatment by fostering independence in patients who had difficulties in self-injection using vial/syringe, while increasing patient satisfaction, as patients showed a preference for use of the InnoLet insulin injection device over the vial and syringe.

**CRD COMMENTARY - Selection of comparators**
A justification was given for using the vial/syringe as the comparator, namely that it represents current practice in the authors' setting. You should decide if the comparator represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a multi-centre, randomised, open-label, two-period crossover trial which was appropriate for the study question. This type of study will limit the problems inherent in studies which look at effects occurring over different periods of time. Using this type of study allows biases, such as improvements in health care patterns over time; better management practices and changes in patients' behaviour over time, will be controlled for. The study sample was representative of the study population. Even though appropriate statistical techniques were used to test for differences between the two interventions, the authors did not always state the p-values associated with the results reported in the study. It is also apparent that the analysis of effectiveness was conducted on treatment completers only.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The analysis was effectively a cost-consequences analysis.

**Validity of estimate of costs**
It was unclear which perspective the authors in the analysis adopted. The only costs included were the costs of nursing/caregiver assistance, and it was unclear if the costs of the insulin injections were included in the analysis. The authors omitted the costs of training patients in the use of InnoLet, as a previous study had reported these to be negligible. However, it is unclear if these omissions will affect the authors' conclusions. Costs and quantities of nursing/caregiver assistance were reported separately, which will enhance generalisability to other settings. Resource use was determined as patients needing nursing/caregiver assistance, which was derived from the study. For resource use, the authors did not report any measures of either variance or the results of any statistical analysis, hence the possible uncertainty in the authors' results. The authors assumed that patients requiring assistance would need three visits per day from the nurse/caregiver, without reporting where this assumption was obtained from, nor allowing for any differences in resource utilisation for patients requiring assistance. In addition, the authors did not report where unit costs were derived from. Statistical analysis of costs was undertaken to test for differences between the two interventions. Since all costs were incurred over a short period of time, discounting was unnecessary. Dates to which prices relate were not reported, which will hamper inflationary exercises. Overall the level of detail reported for the costing was insufficient.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies, which also reported that patients using a vial/syringe had a greater risk of drawing and injecting an inaccurate dose of insulin, and patients preferred InnoLet to other forms of injecting insulin. However, the authors did not explicitly address the issue of generalisability. The authors did not appear to have presented their results selectively, although they not always reported results from the statistical tests performed. The authors' conclusions reflected the scope of the analysis. The authors did
Implications of the study
The authors concluded by stating that their study provided further evidence that an insulin injection delivery device can provide greater positive patient feelings than the traditional vial/syringe.

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Other publications of related interest


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