Sensor-augmented Insulin pump treatment and automatic Insulin suspension vs conventional pump therapy for hypoglycemic unaware patients with type 1 diabetes

Tim Jones*

Department of Endocrinology and Diabetes, Princess Margaret Hospital for Children, Perth, WA, Australia

Corresponding Author*

Tim Jones

Department of Endocrinology and Diabetes, Princess Margaret Hospital for Children, Perth, WA, Australia

E-mail: timlijones@health.wa.gov.au

Received: 25-Jan-2023, Manuscript No. jdm-23-22189; **Editor assigned:** 28-Jan-2023, PreQC No. jdm-23-22189(PQ); **Reviewed:** 11-Feb-2023, QC No. jdm-23-22189; **Revised:** 21-Feb-2023, Revised Manuscript No. jdm-23-22189 (R); **Published:** 28-Feb-2023, DOI: 10.35248/2155-6156.1000980

Abstract

In patients with type 1 diabetes who lack awareness of hypoglycaemia, the objective was to compare the cost-effectiveness of sensor-augmented insulin pump therapy with "Low Glucose Suspend" (LGS) functionality to standard pump therapy with self-monitoring of blood glucose.

Methods: The net costs and effectiveness of the two treatment options were calculated and expressed as an incremental cost-effectiveness ratio (ICER) in an economic evaluation based on a clinical trial. The rate of severe hypoglycaemia in each LGS study arm was the clinical outcome of interest for the evaluation. Personal satisfaction utility scores were determined utilizing the three-level EuroQol five-layered survey. Costs associated with resource use were estimated using public data.

Results: At six months, compared to standard pump therapy, the use of sensor-augmented insulin pump therapy with LGS significantly reduced the incidence of severe hypoglycaemia (incident rate difference 1.85 [0.17–3.53]); P = 0.037). The ICER per severe hypoglycaemic event avoided was $18,257 for all patients in a primary randomized study and $14,944 for patients over the age of 12. The ICERs were $17,602 and $14,289, respectively, when all major medical resource costs (like hospital admissions) were taken into account. For patients over the age of 12, the cost per quality-adjusted life-year gained over the course of the six months was $40,803.

Conclusions: In type 1 diabetes patients who are unaware of their hypoglycaemia, sensor-augmented insulin pump therapy with LGS may be considered a cost-effective alternative to standard pump therapy with self-monitoring of blood glucose. This is based on the Australian experience evaluating new interventions across a wide range of therapeutic areas.

Keywords: Cost-effectiveness; Hypoglycaemia; Insulin pump therapy; Type 1 diabetes

Introduction

In patients with type 1 diabetes who lack awareness of hypoglycaemia, the objective was to compare the cost-effectiveness of sensor-augmented insulin pump therapy with "Low Glucose Suspend" (LGS) functionality to standard pump therapy with self-monitoring of blood glucose. Basal insulin (detemir or glargine) may be administered for 50% of the total insulin dose in patients receiving intensive insulin therapy with MDIs; the rapid acting insulin dose should be determined based on the patient's blood glucose levels and the amount of carbohydrates consumed [1]. The majority of diabetic children require a meal bolus of one unit of rapid-acting insulin for every 10 to 15 g of carbohydrates and a correction bolus of one unit for every 50 to 75 mg/dl of blood glucose above the target. Pre-prandial and two-hour postprandial/correction blood glucose readings must be used to adjust these ratios. The objective reach for blood glucose control should be changed by age. Pre- and post-meal targets for older children should be between 80 and 130 mg/dl. Pre-sleep readings should be between 120 and 150 mg/dl to avoid hypoglycemia in the late night or early morning.

Methods

Participants and comparisons

In December 2012, the Medtronic internal clinical studies database and the MEDLINE, EMBASE, and Cochrane databases were the subject of a systematic literature review to locate existing randomized studies comparing the LGS pump to the standard pump in patients who have impaired hypoglycaemia awareness. This patient populace was picked in light of the fact that the mechanized insulin suspension innovation related to the sensor is of specific importance in this high-risk patient populace. Importantly, this combination of technologies makes it possible to use the integrated RT-CGM pump system in its entirety. As a result, insulin suspension can be initiated when the glucose level reaches a minimum threshold that has been set by the patient or caretaker and the health care professional in order to avoid hypoglycaemic episodes. One study was found in the company database, but no studies were found in the published literature. The authors graciously granted full access to the clinical study data after this study was published. The literature identified four nonrandomized supportive studies but they were not utilized in the economic modelling.

The only randomized study that compares sensor-augmented insulin pump therapy with LGS with standard pump-only therapy and SMBG is the basis for this economic evaluation. The participants in the study were children (n = 31), adolescents (n = 34), and adults (n = 30) with type 1 diabetes who were established pump users (mean age 18.6 11.8 years) and had documented impaired awareness of hypoglycaemia. A modified version of the validated Clarke's questionnaire, which is a validated instrument for measuring this characteristic, was used to identify patients who had impaired awareness of hypoglycaemia. Since two questions were removed, two were rephrased, and units were converted to SI units, the modified version is not validated in its current form [2]. The participants were treated in two tertiary hospitals in Perth, Western Australia, with a mean diabetes duration of 11.0 8.9 years. The results of the efficacy have been published elsewhere. Standard pump therapy with SMBG (standard pump, n = 49) or sensor-augmented insulin pump therapy with automated insulin suspension (LGS pump, n = 46) was randomized to participants, and they were followed for six months. Age stratification was used in the computer-generated randomization [3]. The two groups had similar characteristics at the beginning. The patients who are participating in the clinical study are in line with a group of people with type 1 diabetes who are less aware of hypoglycaemia and are likely to use the technologies being evaluated. During the course of the six-month study, data on hypoglycaemia prevalence and quality of life were collected using the three-level EuroQol five-dimensional (EQ-5D-3L) questionnaire. Because the baseline patient demographic and disease characteristics appear to be representative of the population in which this technology is

being used, we considered the Australian clinical study's findings to be applicable to the local clinical setting without requiring any adjustments [4].

Patients over the age of 12 were the focus of the cost-utility analysis.

Type of evaluation and perspective

A clinical preliminary based financial assessment was performed contrasting the expenses and results related and LGS siphon versus standard siphon treatment. An incremental cost-effectiveness ratio, specifically an incremental cost per quality-adjusted life-year (QALY) gained, is used to describe the outcomes. The analysis was conducted from the perspective of the Australian health care system seeking reimbursement for the RT-CGM Enlite sensor, and only direct costs related to health care were taken into consideration. Because this was a trial-based economic evaluation, costs and outcomes were not discounted beyond the six-month clinical trial. The analysis was not extended beyond the six-month trial period because it would have required various assumptions from multiple non-evidence-based sources at this time, which could have caused uncertainty for a decision-maker making reimbursement decisions [5].

Outcome

The model's diabetes-related outcomes were consistent with the clinical study's definition. The essential clinical end point was the consolidated frequency of serious and moderate hypoglycemic occasions. A hypoglycemic seizure or coma was considered severe hypoglycaemia. A hypoglycemic event that necessitated the assistance of another person was considered moderate hypoglycaemia [6,7]. The pace of moderate hypoglycemic occasions has been accounted for beforehand. Only the rates of severe hypoglycaemia were used in the economic analysis to target the patient population most likely to benefit from LGS pump therapy. According to the clinical study, patients receiving LGS pump therapy had significantly fewer severe hypoglycemic episodes—none—than those receiving standard pump therapy [8].

Results

Over the course of the study, the mean costs and effects of standard pump therapy as well as sensor-augmented insulin pump therapy with automated insulin suspension are presented.

Outcome

During the course of the six-month study, patients in the LGS pump therapy group had zero severe hypoglycemic events, whereas patients in the standard pump therapy group had a significantly higher incidence of severe hypoglycemic events.

Cost-effectiveness

The primary metric for cost-effectiveness is the incremental cost per QALY saved and per severe hypoglycemic event avoided over the course of six months. For all patients in step 1, the incremental cost-effectiveness ratio per avoided event was $18,257, while it was $14,944 for patients over the age of 12. The incremental cost-effectiveness ratio for step 2 was $14,289 for patients over the age of 12 and $17,602 for all patients. For patients over the age of 12, the cost per QALY gained in step 3 was $40,803 over the course of six months. Due to a lack of utility values, no cost per QALY was estimated for patients under the age of 12.

Sensitivity analysis

The economic evaluation's findings were most sensitive to the severe hypoglycemic event rate when all patients and tested variables were taken into consideration. However, the cost-effectiveness ratio did not significantly change when other variables' values were altered. As a result, this analysis's findings may be regarded as reliable provided that the clinical study's severe hypoglycemic event rate is maintained. A similar conclusion can be drawn for those over the age of 12, although the results were most affected by changes in utility values in this age group. The cost-effectiveness ratio only slightly shifts when other variables' values are altered [9].

Discussion

Based on these findings, it appears that the combination of automated insulin suspension and sensor-augmented insulin pump therapy is cost-effective for the high-risk patient population in which a significant clinical benefit was discovered. Our evaluation of cost-effectiveness is based on the Australian health care system's current funding decisions. This is the first financial evaluation of sensor-augmented insulin pump therapy with automated insulin suspension functionality that we are aware of. The cost-effectiveness of insulin pump therapy in comparison to multiple daily insulin injections has been the subject of additional analyses, both in Australia and abroad. When compared to multiple daily insulin doses, sensor-augmented insulin pump therapy (without automated insulin suspension) was not found to be cost-effective in the United States [10]. However, patients with poorly controlled type 1 diabetes were included in that study, and recruitment was not focused on a high-risk population (hypoglycaemia unaware) as in this analysis.

The severe hypoglycaemia incident rate difference, which significantly favored sensor-augmented insulin pump therapy with LGS, is a key driver of the economic analysis. Our economic analysis is based on a clinical study that found a significant difference between the two treatment groups in terms of quality of life, favoring sensor-augmented insulin pump therapy with automated insulin suspension in patient-reported health-related quality of life as measured directly by the validated EQ-5D-3L questionnaire (mean difference in utility 0.0733; 95% CI 0.0075–0.1390; P = 0.0289). Based on the EQ-5D-3L questionnaire for insulin pump therapy, no other study has reported a difference in quality of life, according to our knowledge [11]. Given that severe hypoglycaemia is a serious and much-feared complication of type 1 diabetes, this finding is crucial for effective patient self-management. Indeed, severe hypoglycaemia is thought to be the most significant obstacle to achieving glycemic goals. Others remarked: Patients with type 1 diabetes may benefit from any system that can lessen the severity and duration of nocturnal hypoglycaemia as well as lessen the fear and anxiety associated with it. In addition, it has been reported that the magnitude of the fear of hypoglycaemia is associated with the frequency and severity of severe hypoglycemic episodes, making it an important determinant of health-related utility [12].

Conclusions

The patients in the analysis are a population with a high level of clinical need who are constantly exposed to an increased risk of severe clinical consequences due to frequent medical intervention and the possibility of death. Patients with type 1 diabetes and impaired hypoglycaemia awareness have previously demonstrated the significance of providing access to sensor-augmented insulin pump therapy with automated insulin suspension, which significantly reduces severe hypoglycemic episodes.

The monetary examination of this innovation expects to illuminate outsider payers and leaders that this is likewise a savvy treatment. In a population of type 1 diabetics who are unaware of hypoglycaemia, sensor-augmented insulin pump therapy with automated insulin suspension may be considered an economical alternative to standard pump therapy. Reduced instances of severe hypoglycaemia and associated resource consumption partially offset the costs of this technology.

In a larger, randomized clinical trial with a longer duration, future research should evaluate the clinical and quality of life outcomes of sensor-augmented insulin pump therapy with automated insulin suspension. Other high-risk patient populations, such as those with severe recurrent hypoglycaemia or frequent nocturnal events, may benefit from this technology, which is a significant step toward a fully automated closed loop "artificial pancreas" system. In particular, these patients should be taken into consideration.

Acknowledgement

None

Conflict of Interest

None

References

1. Kedia N. Treatment of severe diabetic hypoglycemia with glucagon: an underutilized therapeutic approach. Diabetes Metab Syndr Obes. 2011; 4: 337-346.
2. Pickup JC, Sutton AJ. Severe hypoglycaemia and glycaemic control in type 1 diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion. Diabet Med. 2008; 25: 765-774.
3. Pickup JC. Insulin-pump therapy for type 1 diabetes mellitus. N Engl J Med. 2012; 366: 1616-1624.
4. Northam EA, Anderson PJ, Jacobs R. Neuropsychological profiles of children with type 1 diabetes 6 years after disease onset. Diabetes Care. 2001; 24: 1541-1546.
5. Rovet JF, Ehrlich RM, Czuchta D. Intellectual characteristics of diabetic children at diagnosis and one year later. J Pediatr Psychol. 1990; 15: 775-788.
6. Ryan C, Vega A, Drash A. Cognitive deficits in adolescents who developed diabetes early in life. Pediatrics. 1985; 75: 921-927.
7. Barnard K, Thomas S, Royle P. Fear of hypoglycaemia in parents of young children with type 1 diabetes: a systematic review. BMC Pediatr.2010; 10: 50.
8. Mattila TK, de Boer A. Influence of intensive versus conventional glucose control on microvascular and macrovascular complications in type 1 and 2 diabetes mellitus. Drugs. 2010; 70: 2229-2245.
9. Ly TT, Gallego PH, Davis EA. Impaired awareness of hypoglycemia in a population-based sample of children and adolescents with type 1 diabetes. Diabetes Care. 2009; 32: 1802-1806.
10. American Diabetes Association. Standards of medical care in diabetes-2013. Diabetes Care. 2013; 36: 6-11.
11. Benhamou PY, Catargi B, Delenne B. Real-time continuous glucose monitoring (CGM) integrated into the treatment of type 1 diabetes: consensus of experts from SFD, EVADIAC and SFE. Diabetes Metab. 2012; 38: 67-83.
12. Ly TT, Hewitt J, Davey RJ. Improving epinephrine responses in hypoglycemia unawareness with real-time continuous glucose monitoring in adolescents with type 1 diabetes. Diabetes Care. 2011; 34: 50-52.

Cite this article: Tim Jones. Sensor-augmented Insulin pump treatment and automatic Insulin suspension vs conventional pump therapy for hypoglycemic unaware patients with type 1 diabetes. J Diabetes Metab, 2023, 14(2): 980.