REDUCED UTILISATION OF HEALTH CARE PROVIDER RESOURCES WITH AUTOMATED BASAL INSULIN TITRATION IN PATIENTS WITH TYPE 2 DIABETES

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INTRODUCTION

- Basal insulin titration in the real world is mostly guided by health care providers (HCP)[1]
- As the physician/HCP visits are usually only once every 3 months, this approach often results in a titration process that can take several quarters or even years[2]
- The long-acting insulin glargine titration tool (LTHome [LTH]) is a web-based interface
  - Based on an algorithm designed to facilitate the HCP-recommended dose progression of basal insulin administration in accordance with a "rules engine"
  - The tool has memory of the plasma glucose values, the suggested insulin glargine doses, and both self-reported insulin glargine dose taken and hypoglycaemia events
- Use of health information technology for insulin titration may offer similar glycaemic effectiveness and lead to reduced utilisation of HCP resources

AIMS

- To evaluate the frequency of contact with a physician or other HCP by patients on basal insulin not meeting local targets or patients requiring basal insulin initiation, using LTH versus enhanced usual therapy (EUT [HCP-driven titration])

METHODS

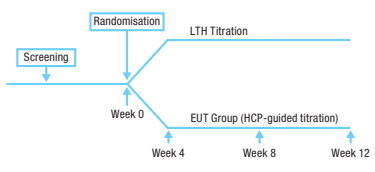
Patients

- Patients with type 2 diabetes mellitus (T2DM), aged 18 to 75 years with body mass index ≤ 45 kg/m^2, A1C > 7.0%, and computer literacy who were scheduled to initiate basal insulin treatment or increase their dose of current basal insulin, independent of study participation, were eligible

Study design

- 12-week, parallel, open-label, randomised, multicentre study to evaluate the use, safety, and effectiveness of LTH versus EUT for glargine titration in patients with T2DM (NCT02540486)
- Data were collected from both groups during scheduled visits at Weeks 4, 8, and 12 (Figure 1)
- Eligible patients were randomised to LTH or EUT and provided education and instruction on insulin dosing (using non-HCP staff) and on use of LTH versus diabetes educator/HCP for EUT of glargine titration
  - Initiation of insulin was taught by designated staff to ensure standardisation of teaching

Figure 1. Study Design



LTH, LTHome web-based interface; EUT, enhanced usual therapy; HCP, health care provider.

- All patients were provided with a plasma-calibrated blood glucose meter (BGStar®), along with strips and lancets
- Fasting plasma glucose values, as well as all events that may have impacted the dose adjustment (ie, hypoglycaemia, increase in routine exercise, change in routine diet), were documented in patient diaries
- Patients in the EUT group titrated their insulin per their HCP's recommendation; those in the LTH group followed the LTH insulin dosing algorithm (Table 1)

Table 1. LTH Insulin Dosing Algorithm

Median FPG Based on Prior 3 Consecutive Results	Dose Adjustment
> 180 mg/dL (10.0 mmol/L)	+4 U every 3 FPG values
> 130 mg/dL (7.2 mmol/L)	+2 U every 3 FPG values
90-130 mg/dL (5.0-7.2 mmol/L)	0
70-88 mg/dL (3.9-4.9 mmol/L)	–2 U or 5%, whichever is greater
< 70 mg/dL (3.9 mmol/L) or any hypoglycaemia symptoms	–4 U or 10%[a], whichever is greater

LTH, LTHome web-based interface; FPG, fasting plasma glucose.
[a]Over a 4-day period.

Study endpoints

- Number of visits to HCP outside of scheduled visits at Weeks 4, 8, and 12
- Change in A1C at Week 12
- Incidence of hypoglycaemia
  - Documented hypoglycaemia was defined as either a blood glucose level < 3.9 mmol/L with or without symptoms, or symptoms of hypoglycaemia without a concomitant blood glucose value
  - Severe hypoglycaemia required the assistance of a third party
- Satisfaction measures included the Hypoglycaemia Fear Survey (HFS) and the Diabetes Distress Scale (DDS)
  - Lower scores indicate greater satisfaction with treatment

Statistical analysis

- Number of contacts with physician/HCP and change from baseline for A1C, HFS, and DDS were analysed by equivalence *t*-test
- Differences between LTH and EUT in the change from baseline for A1C, HFS, and DDS were analysed by *t*-test
- Analysis population was the intent-to-treat population (ie, all enrolled subjects who used LTH ≥ 1 time and administered ≥ 1 dose of insulin glargine in the study)

RESULTS

Patient disposition and characteristics

- A total of 139 patients were randomised; 72 were randomised to LTH and 67 to EUT
- Baseline characteristics were similar between groups (Table 2)

Table 2. Demographic and Clinical Characteristics of Patients

	LTH (n = 72)	EUT (n = 67)
Age, years, mean (SD)	56.4 (8.1)	56.4 (8.4)
Sex, male, n (%)	51 (71)	40 (60)
Ethnic origin, n (%)		
White	40 (56)	28 (42)
South Asian	18 (25)	20 (30)
Weight, kg, mean (SD)	93.2 (20.7)	94.7 (19.9)
Body mass index, kg/m^2, mean (SD)	32.1 (6.0)	33.7 (5.8)
Diabetes duration, years, mean (SD)	11.1 (6.0)	12.9 (7.5)
Insulin requiring		
Titration, n (%)	47 (65)	47 (70)
Initiation, n (%)	25 (35)	20 (30)
Hypertension, n (%)	52 (72)	52 (78)
Cholesterol abnormal/dyslipidaemia, n (%)	65 (90)	62 (93)

LTH, LTHome web-based interface; EUT, enhanced usual therapy.

Glycaemic control

- A1C was 8.8% in both groups at baseline; change from baseline at Week 12 was comparable for both groups ($P = 0.66$) (Figure 2)

Hypoglycaemia

- Incidence of hypoglycaemia was 37% with LTH and 31% with EUT ($P = 0.40$)

Treatment satisfaction

- A significant difference in change from baseline in favour of LTH was observed for both HFS and DDS at 12 weeks (Figure 3)

Figure 2. A1C at Baseline and Week 12 and Change From Baseline – LTH Versus EUT

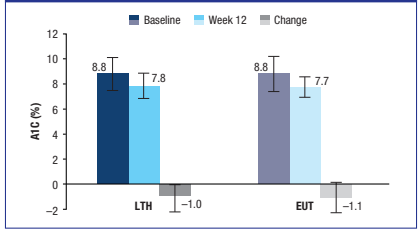


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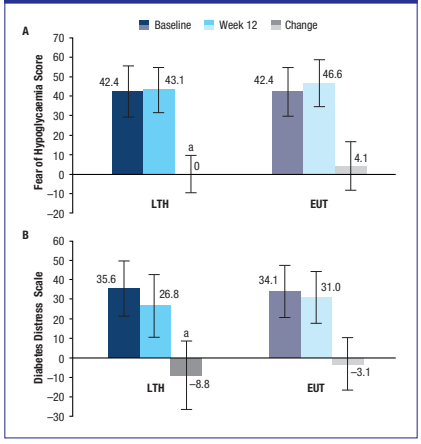
Figure 3. Hypoglycaemia Fear Survey (A) and Diabetes Distress Scale (B) – LTH Versus EUT

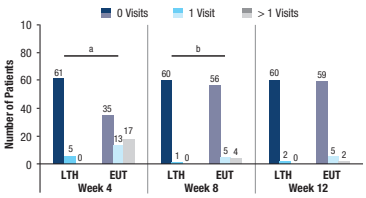


LTH, LTHome web-based interface; EUT, enhanced usual therapy.
[a]$P < 0.05$ vs EUT.

Additional HCP visits

- Fewer patients in the LTH group required additional HCP visits compared with the EUT group (Figure 4)
- The difference between groups was significant at Week 4 and Week 8, but not Week 12

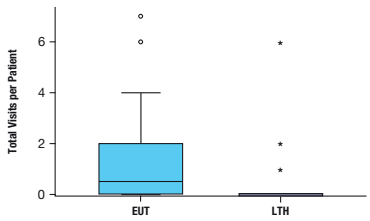
Figure 4. Number of Patients Requiring Additional HCP Visits – LTH Versus EUT



LTH, LTHome web-based interface; EUT, enhanced usual therapy.
[a]$P < 0.0001$; [b]$P < 0.05$ vs EUT.

- Total number of visits for all patients was significantly less with LTH compared with EUT (11 vs 78, $P < 0.001$).
- The mean number of additional visits per patient in each group is shown in Figure 5

Figure 5. Mean Number of Additional Visits Per Patient – EUT Versus LTH



LTH, LTHome web-based interface; EUT, enhanced usual therapy.

CONCLUSION

- Automated basal insulin titration led to reduced HCP resource utilisation and improved patient satisfaction, while providing similar glycaemic safety and effectiveness

REFERENCES

1. Strange P. *J Diabetes Sci Technol.* 2007;1:540-548.
2. Morrison F, et al. *Arch Intern Med.* 2011;171:1542-1550.

DISCLOSURES

J. Sieber and **F. Flacke** are employees of Sanofi-Aventis Deutschland GmbH. **H. Bajaj** served as an advisor to AstraZeneca, Janssen Pharmaceuticals, Merck & Co., Novo Nordisk, and Sanofi U.S.; he received research support from AstraZeneca, Boehringer Ingelheim GmbH, Eli Lilly and Company, Genkyotex, Janssen Pharmaceuticals, Merck & Co., Pfizer, Novo Nordisk, Regeneron Pharmaceuticals, and Sanofi U.S.; speaker's bureau for Abbott, AstraZeneca, Bayer HealthCare, Boehringer Ingelheim GmbH, Eli Lilly and Company, Janssen Pharmaceuticals, Medtronic, Merck & Co., Novo Nordisk, Sanofi U.S., and Valeant Pharmaceuticals. **K. Venn and T. Kottman** report nothing to disclose. **R. Aronson** served as an advisor to Novo Nordisk A/S, Janssen Pharmaceuticals, Sanofi U.S., Medtronic, and AstraZeneca, and as a consultant for Novo Nordisk A/S, Janssen Pharmaceuticals, Sanofi U.S., Medtronic, and AstraZeneca; he received research support from BD Medical-Diabetes Care, Sanofi U.S., Merck & Co., Janssen Pharmaceuticals, Medtronic, AstraZeneca, Novo Nordisk A/S, Eli Lilly and Company, Quintiles, ICON, Lexicon Pharmaceuticals, GlaxoSmithKline, Genkyotex, PAREXEL International, Covance, Pfizer, inVentiv Health, and AbbVie; other relationship with Sanofi U.S.

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