PDB3

The Real-World Observational Prospective Study of Health Outcomes with Dulaglutide and Liraglutide in Type 2 Diabetes Patients (TROPHIES): 6-month analysis results

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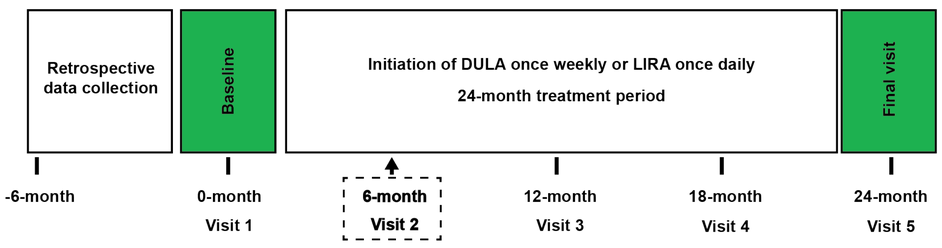
OBJECTIVE

TROPHIES is a 24-month, prospective, observational study in patients with type 2 diabetes (T2D) initiating their first injectable treatment with the glucagon-like peptide-1 receptor agonists (GLP-1 RA) dulaglutide (DULA) or liraglutide (LIRA)

The objective of this poster is to report the 6-month analysis results, with a particular focus on the change in HbA1c and weight in T2D patients 6 months after starting DULA or LIRA

The treatment patterns at Baseline and 3-month and utilization of oral glucose lowering medication (GLM) at 1-month is also presented

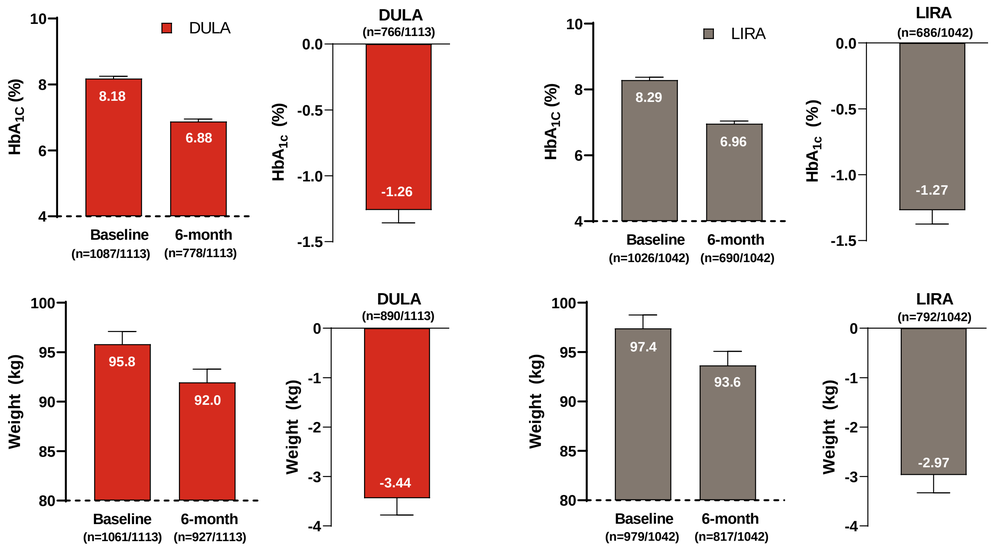
STUDY DESIGN



- **Design:** 24-month, prospective, non-comparative, observational study
- **Location:** France, Germany, and Italy
- **Population:** Adult patients with T2D initiating their first injectable antihyperglycemic treatment with either DULA or LIRA, and who were naïve to any injectable treatment were included
- At 6-month (**Visit 2**), HbA_{1c} levels, weight, GLP-1 RA treatment patterns and status of oral glucose lowering medications (GLMs) were assessed

KEY RESULT

HbA_{1c} and weight change from Baseline to 6-month



Graphs show the absolute and change from Baseline to 6-month HbA_{1c} (top) and weight (bottom) in the DULA (left; red) and LIRA (right; gray) cohorts. For both HbA_{1c} and weight, the total population size is 1113 patients in the DULA cohort and 1042 patients in the LIRA cohort. Values within parenthesis describe the number of patients for which data was collected / total population size. Error bars represent a 95% CI.

- Both the DULA and LIRA cohort displayed a decrease in HbA_{1c} and weight at 6-month compared to Baseline

Background

- Treatment of T2D involves the use of GLM to achieve glycemic targets combined with healthy lifestyle changes[1]
- GLP-1 RA are an injectable therapy recommended for T2D that offer improved glycemic control plus additional benefits including weight reduction[2,3]
- Several GLP-1 RA are available each displaying different profiles with regards to effectiveness, tolerability and ease of dosing
- Observational studies, such as TROPHIES, are needed to evaluate and better understand the treatment patterns and persistence of GLP-1 RA

Study Objectives

- Primary objective: To estimate the time patients remain on their first GLP-1 RA without a ***significant treatment change*** due to treatment- or diabetes-related factors*
- Secondary objective: To report patient characteristics, treatment patterns, factors associated with the first significant treatment change, key clinical outcomes, health-related quality of life and other patient reported outcomes and resource use associated with treatment for T2D

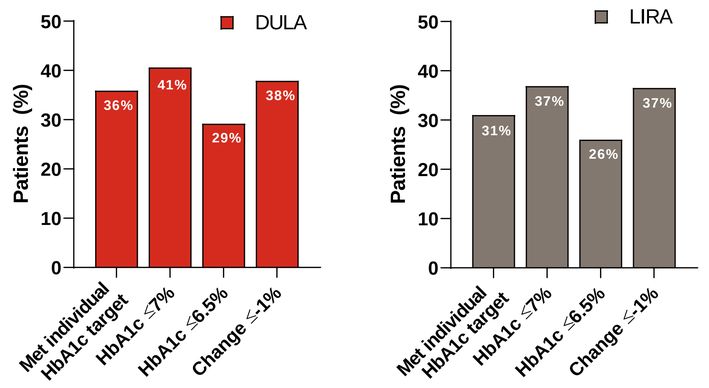
* For more details on the definition of ***significant treatment change***, refer to the recent publication by Boye *et al.* 2020[4] which describes the patient reported outcomes for TROPHIES at Baseline

Study Population

- Key eligibility criteria
  - Aged ≥18 years and diagnosed with T2D
  - Presented during the normal course of care when a decision was made to initiate treatment with DULA / LIRA
  - Naïve to injectable treatment for T2D
- Key exclusion criteria
  - Patients that started insulin simultaneously with GLP-1 RA at Baseline

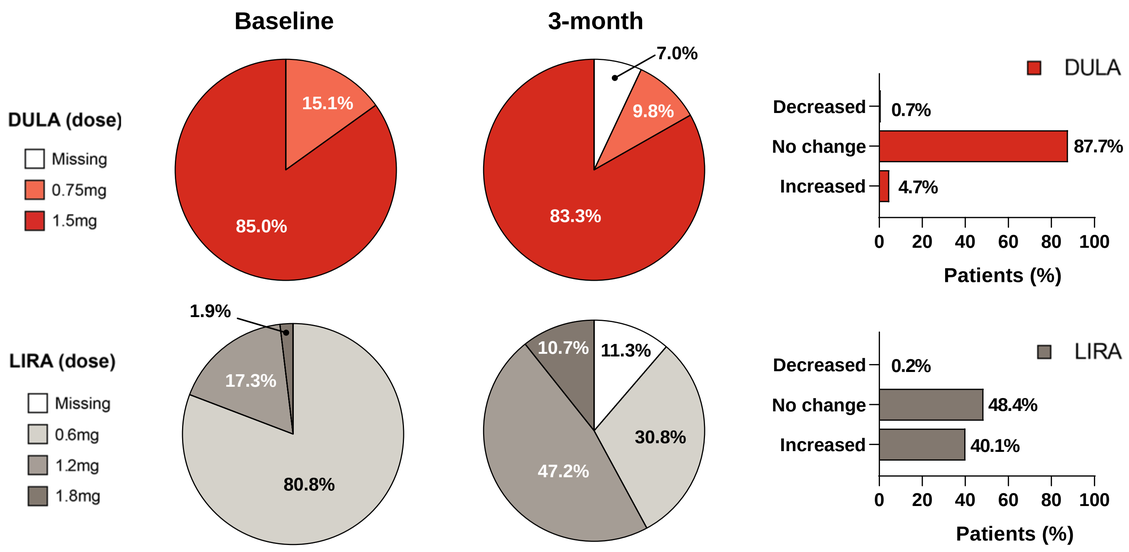
Additional Results

HbA_{1c} targets and changes



- Individual HbA_{1c} targets were set by the prescribing physician at Baseline for his/her patient.
- At 6-month, 400 (35.9%) DULA patients and 323 (31.0%) LIRA patients met their individual HbA_{1c} targets.
- Patients in each cohort achieving HbA_{1c} <7% and ≤6.5% is also highlighted

Summary of GLP-1 RA dose at Baseline and 3-month



Pie-charts on the left describe the proportion of patients taking either DULA (0.75mg or 1.5mg) and LIRA (0.6mg, 1.2mg and 1.8mg) at Baseline and 3-month. The graphs on the right show the proportion of patients who increased, decreased or had no change in the dose of GLP-1 RA.

- The majority of DULA patients were taking 1.5mg DULA at Baseline and at 3-month
- By 3-month, 4.7% of DULA patients increased their dose while 87.7% remained on the dose prescribed at Baseline
- The most common dose of LIRA at Baseline was 0.6mg while at 3-month the most common dose was 1.2mg
- In the LIRA group, 40.1% of patients increased their dose by 3-month with 48.4% remaining on the dose prescribed at Baseline
- Maximum GLP-1 RA dose between Baseline and 3-month:
  - The maximum DULA dose was 1.5mg for 90% of patients in the DULA cohort
  - The maximum LIRA dose was 0.6mg for 36% of patients, 1.2 mg for 51% and 1.8mg for 13%

Utilization of oral GLM at 1-month

- Between Baseline and 1-month, the number of patients taking 3 oral GLM decreases (from n=145 to n=63) while the number of patients with one 1 oral GLM increases (from n=1152 to n=1258)
- Metformin remains the main oral GLM at 1-month (77.4% of patients)
- The number of patients taking sulfonylureas and DPP-4 inhibitors decreases between Baseline and 1-month (sulfonylureas, from n=434 to n=412; DPP-4 inhibitors, from n=293 to n=140)

Limitations

- The current results are descriptive and further analyses with the necessary adjustments are required
- Limitations are due to the observational / non-interventional nature of the study

CONCLUSIONS

At 6-month, patients in the DULA or LIRA cohort showed a decrease in HbA_{1c} and a weight change in line with clinical trial results

- From Baseline to 6-month, HbA_{1c} decreased by -1.3 (SD±1.4)% in both the DULA and LIRA cohort
- 35.9% of DULA patients and 31.0% of LIRA patients reached their individual HbA_{1c} target set by the physician
- At 6-month, the mean weight change for DULA was -3.44kg while the mean weight change for LIRA was -2.97kg

References:

1. American Diabetes Association. Standards of Medical Care in Diabetes - 2018. *Diabetes Care* 2018; **41**(S1).
2. Dungan KM, et al. *The Lancet* 2014; **384**(9951) 1439-1357.
3. Drucker DJ, et al. *The Lancet* 2006; **368**(9548) 1696-1705.
4. Boye KS, et al. *Diabetes Therapy* 2020; **11**(10) 2383-2399.

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