PDB82

The Real-World Observational Prospective Study of Health Outcomes with Dulaglutide and Liraglutide in Type 2 Diabetes Patients (TROPHIES): Country-Specific Baseline Characteristics

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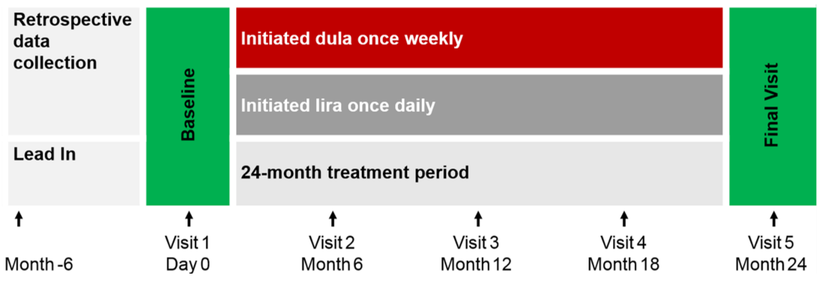
OBJECTIVE

To describe the baseline characteristics of patients with type 2 diabetes (T2D), starting their first injectable treatment with glucagon-like peptide-1 receptor agonists (GLP-1 RA) either with once-weekly dulaglutide (dula) or once-daily liraglutide (lira), in France, Germany, and Italy

STUDY DESIGN



- TROPHIES is a 24-month, prospective, observational study conducted in France, Germany, and Italy
- Adult patients with T2D initiating their first injectable antihyperglycemic treatment with either dula or lira, and who were naive to any injectable treatment were included
- At baseline, demographics, duration of T2D, HbA_{1c} levels, reported HbA_{1c} targets, pre-existing diabetes-related diagnoses, and concomitantly used oral glucose-lowering medications (GLMs) were assessed

KEY RESULT

Baseline demographics and glycemic characteristics by country

Characteristics	France Dula N=377	France Lira N=335	Germany Dula N=389	Germany Lira N=353	Italy Dula N=389	Italy Lira N=353
BMI, mean (SD), kg/m²	32.87 (6.10)	33.81 (6.13)	35.75 (7.41)	36.18 (6.92)	32.67 (5.81)	32.44 (5.97)
Duration of T2D, mean (SD), years	8.49 (6.76)	9.47 (7.57)	7.41 (6.25)	6.24 (5.68)	9.72 (7.39)	9.44 (6.97)
HbA_{1c}, mean (SD)						
n	368	329	361	354	373	349
%	8.51 (1.36)	8.59 (1.48)	8.04 (1.36)	8.26 (1.50)	8.02 (0.66)	8.04 (0.85)
mmol/mol	69.5 (14.87)	70.38 (16.17)	64.36 (14.87)	66.77 (16.40)	64.15 (7.21)	64.36 (9.29)
Reported HbA_{1c} target, mean (SD)						
n	375	332	363	362	387	352
%	6.93 (0.44)	6.92 (0.33)	6.83 (0.38)	6.82 (0.42)	6.84 (0.32)	6.82 (0.31)
mmol/mol	52.23 (4.81)	52.12 (3.61)	51.14 (4.15)	51.03 (4.59)	51.25 (3.50)	51.03 (3.39)
HbA_{1c} level difference at baseline and target, mean (SD)						
n	368	329	361	354	373	349
%	1.59 (1.30)	1.67 (1.43)	1.21 (1.25)	1.45 (1.40)	1.16 (0.65)	1.22 (0.87)
mmol/mol	6.14 (14.21)	5.27 (15.63)	10.30 (13.66)	7.67 (15.30)	10.84 (7.11)	10.19 (9.51)
Diabetes-related medical conditions, n (%)						
n	377	335	364	363	389	353
Macrovascular[a]	17 (4.5)	55 (16.4)	24 (6.6)	20 (5.5)	52 (13.4)	48 (13.6)
Microvascular[b]	44 (11.7)	50 (14.9)	87 (23.9)	53 (14.6)	64 (16.5)	54 (15.3)
Hyperlipidemia	234 (62.1)	227 (67.8)	222 (61.0)	204 (56.2)	263 (67.6)	234 (66.3)
Hypertension	237 (62.9)	234 (69.9)	295 (81.0)	281 (77.4)	281 (72.2)	268 (75.9)

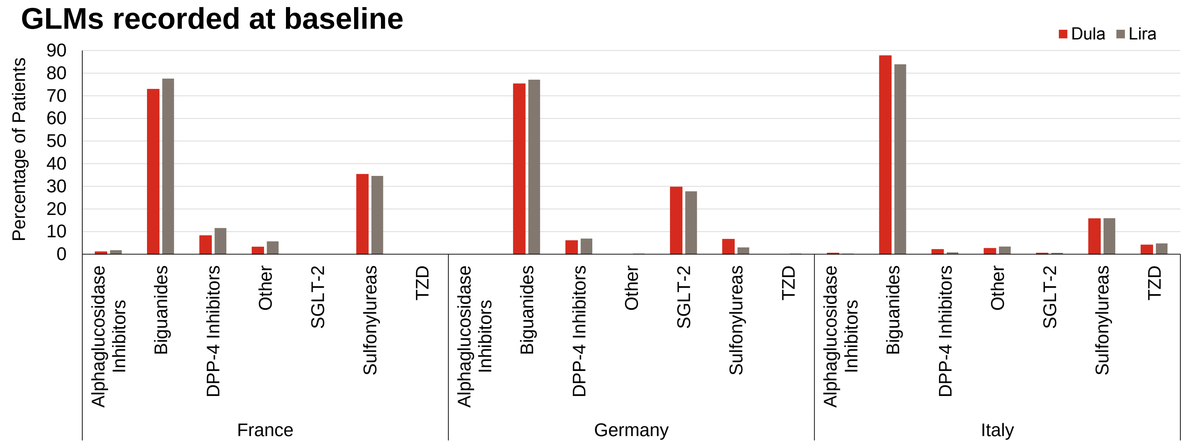
[a]Includes patients with cerebrovascular disease, congestive heart failure, dementia, hemiplegia or paraplegia, myocardial infarction, and peripheral vascular disease at baseline.
[b]Includes patients with macroalbuminuria, microalbuminuria, nephropathy, neuropathy, and retinopathy at baseline.
BMI=Body Mass Index; HbA1c, glycated haemoglobin; N=total population size; n=number of patients; SD standard deviation.

Note: Data for missing patients are insignificant for the characteristics presented in this poster.

Additional Results

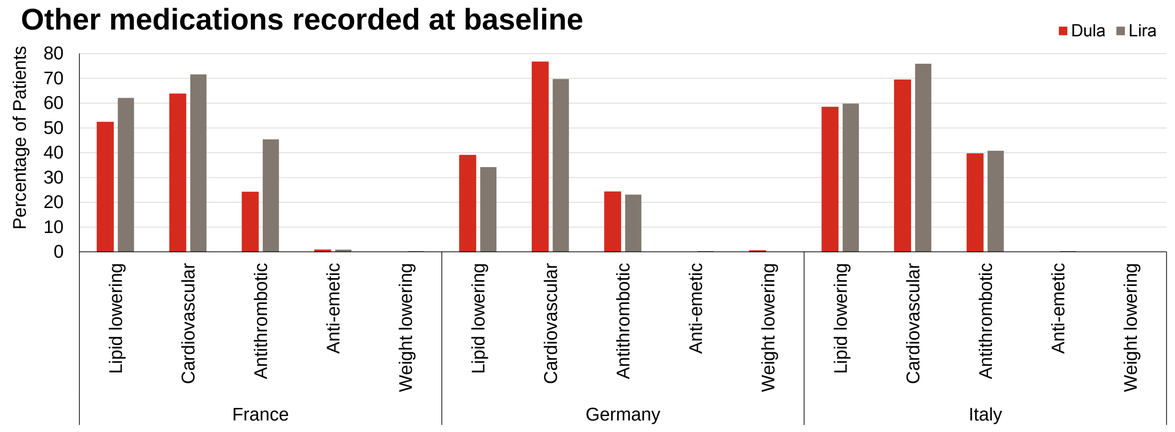
- The mean age and gender distribution were similar between cohorts, in France, Germany, and Italy

GLMs recorded at baseline



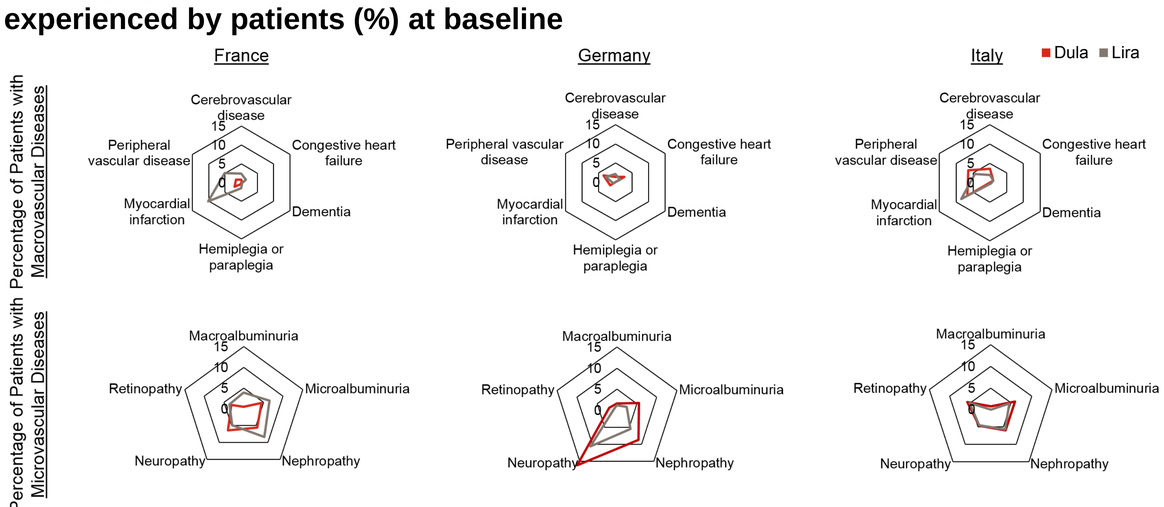
- The class of biguanides is the most prescribed GLM class across the different patient groups. The next most prescribed GLM class in both France and Italy is the class of sulfonylureasSodium glucose cotransporter-2 (SGLT-2) inhibitors, which are not available in France, are the second most prescribed in Germany.

Other medications recorded at baseline



- Cardiovascular medications are the most prescribed non-diabetes-related medications in both cohorts and in the 3 countries

Country-specific macrovascular and microvascular diabetes-related conditions experienced by patients (%) at baseline



- Myocardial infarction was most prevalent in lira cohorts in both France and Italy (10.1% and 8.5%, respectively), whereas neuropathy was reported more often in Germany (16.2% and 10.7% of the dula and lira cohorts, respectively)

Background

- The treatment of patients with T2D involves a stepwise approach, beginning with lifestyle interventions, to achieve glycemic targets[1]
- Single agent or combination treatment is recommended when targets are not achieved[1]
- GLP-1 RAs have emerged as the first injectable therapy recommended for T2D, offering improved glycemic control and other health benefits[2,3]
- Observational studies, such as TROPHIES*, are useful for collecting real world data; measuring patient characteristics and evaluating the impact of country-specific reimbursement policies and treatment patterns from baseline

Study Objectives

- Primary objective is 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 objectives include 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

Study Population

Selection of physicians and key selection criteria for patients

- Physicians eligible to participate in TROPHIES treat patients with T2D, and are allowed to prescribe GLP-1 RA. Physician specialties and selection process were dependent on country regulatory requirements and healthcare systems.
- Patient key selection criteria
  - Aged ≥18 years with T2D
  - Presented during the normal course of care
  - Naive to injectable treatment for T2D

CONCLUSIONS

For each country, TROPHIES highlights the patient characteristics at baseline, who were prescribed dulaglutide or liraglutide

- At baseline, for all cohorts of patients from France, Germany, and Italy
  - Age and gender distribution were similar, while T2D duration differed slightly between countries
  - HbA1c levels surpassed reported targets and this supported intensification of treatment with GLP-1 RA prescription
  - Mean BMI values reflected obese populations, with patients more obese in Germany than Italy and France
- Differences were observed in prescribed oral GLMs, in addition to lipid lowering and antithrombotic medications, which may be due to country-specific clinical guidelines and restrictive reimbursement policies
- Diabetes-related conditions varied in patient cohorts across countries
- TROPHIES highlights the country-specific differences of patients at baseline and prescribed dulaglutide or liraglutide

*See posters **PDB116** and **PDB113** for the TROPHIES study design and patient-reported outcomes at baseline.

References:
1. American Diabetes Association. Standards of medical care in Diabetes 2018. *Diabetes Care*. **41**, S1 (2018).
2. Dungan KM, *et al*. *The Lancet*. **384:9951**, 1439-1357 (2014).
3. Drucker DJ, *et al*. *The Lancet*. **368:9548**, 1696-1705 (2006).

Acknowledgments: Eli Lilly and Company participated in design, data collection, analysis and reporting results. The authors would like to thank Róise McGovern, PhD, an employee of Eli Lilly and Company, for writing and editorial contributions.

Disclosures: K.B., L.E.G-P., H.S., M.R., M.O.F., E.H., H.J. and K.N. are full-time employees and shareholders of Eli Lilly and Company; R.G. and U.A. have no disclosures to declare. F.G. 1) provides research support for Eli Lilly; Lifescan, Takeda; 2) is a consultant for Boehringer Ingelheim; Lifescan; Merck Sharp & Dohme; Sanofi; AstraZeneca; Medimmune; Roche Diabetes Care; and 3) on the advisory boards for AstraZeneca; Eli Lilly; Novo Nordisk; Roche Diabetes Care; and Sanofi. B.G. 1) provides research support for Medtronic; Vitalaire; Sanofi; Eli Lilly; Novo Nordisk; 2) is a Clinical investigator for Sanofi; Eli Lilly; NovoNordisk; GSK; BMS; AstraZeneca; Medtronic; Abbott; Roche Diagnostics; MSD; Novartis; Janssen; Boehringer Ingelheim and 3) is an Advisory panel/board member for Sanofi; Eli Lilly; NovoNordisk; Novartis; GSK; MSD; Boehringer Ingelheim; AstraZeneca; Abbott; Medtronic; Roche Diagnostics.

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ISPOR-EU 2019

International Society for Pharmacoeconomics and Outcomes Research; Copenhagen, Denmark; November 2 – 6, 2019

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