The PANORAMA European Study: Biomedical and Psychological Characteristics of People with Type 2 Diabetes with and without Obesity

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Introduction

- Obesity is a major modifiable risk factor in the prevention of type 2 diabetes (T2D). The prevalence of T2D has been shown to increase with increasing body mass index (BMI).[1] In the US adult population nearly one-quarter of adults with diabetes have poor glycaemic control, and nearly half of all adult patients with diabetes are considered obese.[1]
- In Europe, the prevalence of obesity has been reported to range from 4.0% to 28.3% in men and from 6.2% to 36.5% in women, with greater prevalence in countries in Eastern Europe and the Mediterranean than in countries in Western and Northern Europe.[2]
- It is well established that patients with T2D are at an increased risk of cardiovascular disease (CVD),[3] as are patients with obesity.[4] Patients with T2D who are also obese have increased frequencies of dyslipidaemia, hypertension, and microalbuminuria, which are well-known cardiovascular risk factors.[5]
- PANORAMA is a large European, multicentre, multinational, cross-sectional study (NCT00916513) of patients with T2D aimed at assessing treatment satisfaction, quality of life (QoL) and other patient-reported outcomes (PROs) in relation to glycaemic control. All patients received diet/exercise advice and most patients were treated with glucose-lowering therapies. This analysis compares results between obese (BMI ≥30) and non-obese (BMI <30) patients.

Methods

- To achieve a representative sample of primary care physicians that reflected country-specific clinical practices, a random selection procedure was applied to databases of primary care physicians taking care of patients with T2D in each country. Comprehensive lists of physicians were obtained (whenever possible using data from national authorities, local scientific societies or professional associations). Where necessary, the proposed selection strategy was adapted to the specific characteristics of some countries leading to the inclusion of specialists in Italy and Greece specifically.
- Patients with T2D were then randomly or consecutively selected from these physician practices. Informed consent was obtained before inclusion.
- *Study population:* Patients aged ≥40 years, with a diagnosis of T2D for >1 year prior to study entry and an available medical record at the clinic of >1 year.
- *Key exclusion criteria:* Patients with type 1 diabetes and/or a history of diabetic ketoacidosis, or secondary diabetes (including disease of the exocrine pancreas, endocrinopathies or drug-induced).
- At the study visit, information was collected from participating patients and from their medical records (with a maximum retrospect of 2 years).

Assessments

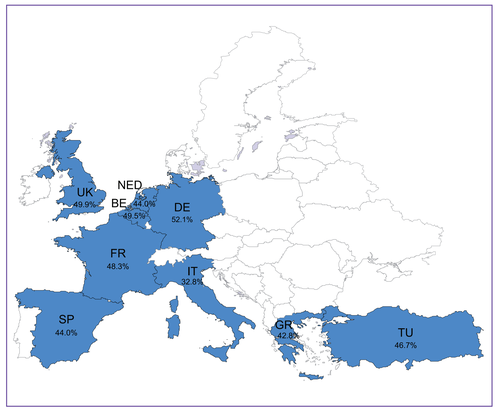
- Data collected included patient socio-demographics, disease-related variables, biological measures, (including HbA_{1c} measured using a standard device [see following bullet]), PROs, health-economic variables, physician-reported endpoints, and physician socio-demographics. An electronic case report form (paper version also available) was provided for the collection, monitoring and processing of these data. All study procedures were carried out in accordance with Good Clinical Practice.
- HbA_{1c} levels were measured using a point-of-care device (Bayer's A1CNow®). This device is certified by US National Glycohemoglobin Standardization Program.
- To assess PROs, patients completed the following questionnaires (in their preferred language) – the Audit of Diabetes-Dependent Quality of Life (ADDQoL),[6,7] the Diabetes Treatment Satisfaction Questionnaire (DTSQ),[8,9] the Hypoglycemia Fear Survey (HFS-II)[10,11] worry subscale and the European Quality of Life-5 Dimensions (EQ-5D).[12]
- The ADDQoL, DTSQ, HFS-II worry subscale and EQ-5D have previously been linguistically validated including cultural adaptation involving forward and back translation, with author review of back translations, revisions as needed, clinician review of revision, cognitive debriefing with patients and international harmonisation.

Results

Patient characteristics

- 5,817 patients were recruited across nine different countries (Belgium, n=659; France, n=760; Germany, n=808; Greece, n=374; Italy, n=752; The Netherlands, n=611; Spain, n=752; Turkey, n=600; UK, n=501). The proportion of patients from each participating country with a BMI ≥30 is shown in Figure 1.

Figure 1. Proportion of patients with a BMI ≥30



- Patient characteristics according to categories of BMI can be found in Table 1.

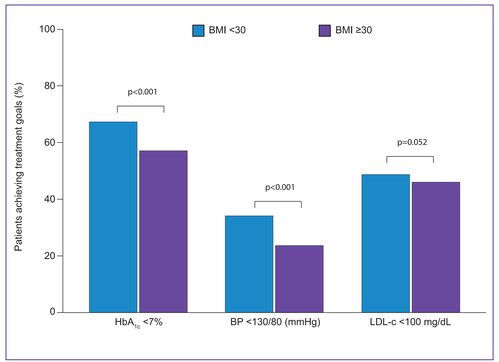
Table 1. Patient characteristics according to categories of BMI

	BMI <30	BMI ≥30	p-value
Participants; N (%)	3,165 (54.4)	2,650 (45.6)	
Age (years); mean (±SD)	67.25 (10.4)	64.23 (10.1)	<0.001
Male; N (%)	1,861 (58.8)	1,262 (47.6)	<0.001
Leaving full time education >18y; N (%)	797 (25.2)	576 (21.7)	<0.001
Current smoker; N (%)	495 (15.6)	338 (12.8)	0.002
Diabetes duration; mean (±SD)	9.23 (7.4)	8.49 (6.8)	<0.001
Microvascular complications; N (%)	846 (26.7)	809 (30.5)	0.001
Depressive disorders; N (%)	375 (11.9)	425 (16.0)	<0.001
Sleep disorders; N (%)	369 (11.7)	464 (17.5)	<0.001

Treatment goals

A greater number of patients with BMI <30 met targets for glycaemic control (HbA_{1c} <7%; p<0.001), blood pressure (<130/80 mmHg; p<0.001) and lipids (LDL-c <100 mg/dL; p=0.052) than patients with a BMI ≥30 (Figure 2).

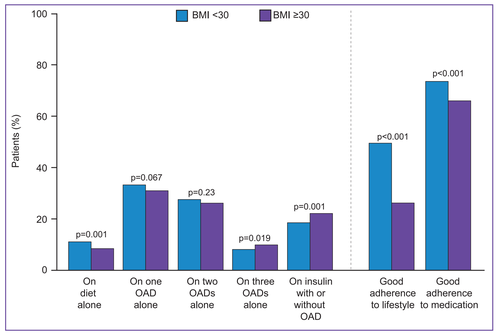
Figure 2. Goal attainment according to categories of BMI



Treatment patterns

- Figure 3 shows that significantly more patients with a BMI <30 were treated with diet alone (p=0.001) compared with patients with a BMI ≥30. In contrast, significantly more patients with a BMI ≥30 were treated with three oral antidiabetes agents (OADs) alone, or with insulin ± OAD than patients with a BMI <30 (p=0.019 and p=0.001, respectively). A significantly greater number of patients with BMI <30 were rated by their physician to have good adherence to lifestyle and medication compared with patients with a BMI ≥30 (both p<0.001; Figure 3).

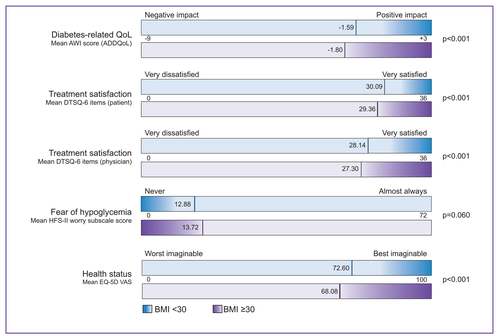
Figure 3. Treatment patterns and levels of physician-reported treatment adherence according to categories of BMI



Patient-reported outcomes

- Figure 4 compares the PRO measures in the PANORAMA study between obese and non-obese patients. The overall mean of the ADDQoL average-weighted impact (AWI) score was significantly more negative for patients with a BMI ≥30 (-1.80) compared with patients with a BMI <30 (-1.59, p<0.001) indicating that patients with a BMI ≥30 rated their QoL as more negatively impacted by diabetes than patients with a BMI <30.
- Patients with a BMI ≥30 were significantly less satisfied (29.36 [possible maximum of 36]) with their treatment (DTSQ-6 items) compared with patients with a BMI <30 (30.09, p<0.001; Figure 4). Physicians also rated the treatment satisfaction of patients with a BMI ≥30 significantly lower (p<0.001) than patients with a BMI <30 (27.30 vs 28.14, respectively; Figure 4).

Figure 4. Patient-reported outcome measures according to categories of BMI



- Patients with a BMI ≥30 were more concerned about hypoglycaemia than patients with a BMI <30 (mean scores 13.72 vs 12.88 [out of a maximum of 72]).
- The health status reported by patients with a BMI <30 was significantly better (p<0.001) than that reported by patients with a BMI ≥30 (72.60 vs 68.08, respectively [scale 0 to 100]).

Discussion

- Patients with a BMI ≥30 reported a significantly more negative impact of diabetes on their QoL, less satisfaction with treatment and lower health status, than patients with a BMI <30 (all p<0.001). They were also more concerned about hypoglycaemia than patients with a BMI <30.
- Significantly more patients with a BMI ≥30 were treated with three OADs or with insulin ± OAD than patients with a BMI <30. However, this is not explained by disease duration as patients with a BMI <30 had a significantly longer disease duration compared with patients with a BMI ≥30 (p<0.001).
- These comparative analyses are unadjusted, further analyses are needed to adjust for confounding factors.

Conclusions

- Obesity in patients with T2D was associated with a greater prevalence of co-morbidities (depressive and sleep disorders), microvascular complications, and poorer glycaemic, lipid and blood pressure control.
- Physicians rated obese patients as much less adherent to lifestyle advice and somewhat less adherent to medication.
- PRO measures showed more negative responses in obese patients.
- These results highlight the importance of effective weight management in the treatment of patients with T2D, and suggest that improved efforts to tailor treatments to individual profiles may be beneficial for obese patients.

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Access to Questionnaires

The HFS-II can be obtained from the copyright holder, Linda Gönder-Frederick, at lag3g@virginia.edu.

Details of the items and layout of the DTSQ and ADDQoL may be found at http://www.healthpsychologyresearch.com and details of the EQ-5D may be found at http://www.euroqol.org.

Acknowledgements

The PANORAMA study was funded by AstraZeneca and Bristol-Myers Squibb. Editorial assistance was provided by Eleanor Steele, BSc, and Max Frenzel, PhD, of QXV Communications, Macclesfield, UK, funded by AstraZeneca and Bristol-Myers Squibb.

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