**Introduction**

- At present, the number of people with diabetes in Germany is estimated to be 7.6 million, approximately 9.6% of whom suffer from type 2 diabetes (T2D)\(^\text{1}\).
- To evaluate therapeutic efficacy in daily clinical practice and the state of T2D patient care, non-interventional studies (e.g., registry studies) are frequently conducted\(^\text{2}\). Using registries, course and duration of therapy and resource expenditure from routine care can be measured and used to illustrate the real-world state of patient care\(^\text{3}\).
- Thus far, however, quality of life (QoL) and subjective patient well-being have frequently been neglected. Furthermore, several diabetes registries only include a limited timeframe or certain patient groups (e.g., DIVE, DuPageS, DIABOLIC\(^\text{4}\)). Moreover, registries based on data from routine clinical practices are frequently incomplete (e.g., data on body-mass-index [BMI] or HbA1c) and do not consider behavioural aspects.
- The aim of the DIAREG registry is the comprehensive mapping of real-world T2D patient care in Germany with a special emphasis on subjective patient well-being and Patient-Reported Outcomes (PROs).

**Methods**

- The DIAREG T2D registry was initiated in July 2013 as part of a cooperation between AstaZeneca GmbH and IMS\(^\text{5}\), supported by the Association of Nordrhein, Germany.
- DIAREG is based on the combined, self-complimentary recording and processing of retrospective WHO Health Database with guidance by a scientific advisory board. AstaZeneca and IMS\(^\text{6}\) and prospective data from physician questionnaires (electronic Case Report Forms, eCRFs) as well as validated patient questionnaires (Patient-Reported Outcomes, PROs)\(^\text{7}\).
- Patients included in the DIAREG registry provided informed consent on the anonymised merging\(^*\) and evaluation of information obtained from EMRs, eCRFs and PROs. The registry protocol has been approved by the ethics committee of the Medical Association of Northrhine, Germany.
- DIAREG is registered with ClinicalTrials.gov (NCT01906294).
- eCRFs were triggered randomly according to estimated frequency and severity of hypoglycaemia as part of a cooperation between AstraZeneca and IMS\(^\text{5}\).
- DIAREG – Diabetes Register including Patient-Reported Outcomes

**Results**

- By the end of June 2015, complete data for approximately 1,800 patients with T2D were available (overall cohort). These comprise an observational period of 22 months (August 2013 – June 2015). From August 2014 until June 2015 PROs from 270 patients (PRO cohort) could be obtained.

**Conclusions**

- This initial PRO subgroup analysis is cross-sectional in nature, and longitudinal analyses are required to obtain results regarding patient QoL and therapy quality or changes over the course of the disease.

**Limitation**

- DIAREG is the first registry in Germany reporting comprehensive subjective PRO data in combination with clinical characteristics of patients with T2D in primary and specialist care.

- Initial results from the PRO cohort show an increased depression score at a short duration of diabetes (<2 years) and a reduced QoL in very obese patients BMI >40. There was no correlation between QoL and HbA1c control and type of antidiabetic therapy.

**Future longitudinal analyses will focus on the correlation between:**

- QoL, depression and quality of diabetes control (HbA1c, hypoglycaemic events);
- QoL, depression and therapy adherence;
- Change in QoL and depression after change of therapy (novel vs. classical antidiabetic drugs).

**Supporting Information**

- Evidence for the use of the Disease Analyzer as a Patient-Reported Outcomes (PRO) tool for diabetes care evaluation\(^\text{8}\).

**Authors' Contribution**

- Michael Hahn, Henrike Götte and Stefan Busch

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**Table 1:** Overview of comprehensive information gathered by DIAREG.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>DIAREG overall</th>
<th>PRO cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>1,807</td>
<td>270</td>
</tr>
<tr>
<td>Age, years (SD)</td>
<td>68.7 (10.6)</td>
<td>68.1 (10.2)</td>
</tr>
<tr>
<td>Sex</td>
<td>Male, %</td>
<td>52.3</td>
</tr>
<tr>
<td></td>
<td>Female, %</td>
<td>47.7</td>
</tr>
<tr>
<td>Health insurance coverage, %</td>
<td>56.5</td>
<td>56.5</td>
</tr>
<tr>
<td>Treatment by specialist, %</td>
<td>60.9</td>
<td>60.9</td>
</tr>
<tr>
<td>BMI, kg (SD)</td>
<td>30.6 (5.1)</td>
<td>30.7 (5.0)</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>7.0 (1.3)</td>
<td>7.0 (1.3)</td>
</tr>
<tr>
<td>Hypoglycaemia since last visit, %</td>
<td>2.2</td>
<td>2.7</td>
</tr>
<tr>
<td>Insulin therapy, %</td>
<td>36.3</td>
<td>36.3</td>
</tr>
<tr>
<td>Metformin, %</td>
<td>56.1</td>
<td>46.0</td>
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<tr>
<td>DPP-4i, %</td>
<td>19.6</td>
<td>21.8</td>
</tr>
</tbody>
</table>

**Table 2:** Announced parameters of the DIAREG overall and PRO cohort (2015)

- No significant correlation between BMI and depression score at a short duration of diabetes (≤2 years), also when adjusted according to patient age and sex (Figure 3).

**Figure 1:** Overview of comprehensive information gathered by DIAREG.

**Table 3:** Parameter characterisation of interest in the Disease Analyzer trigger PRO.

**Table 4:** Subgroup analysis results of the PRO cohort.

**Figure 2:** Pooled data of change of medication by DIAREG (n = 57).

**Figure 3:** CES-D questionnaire stratified by duration of T2D in the PRO cohort (n = 270).

**Figure 4:** Scatter plots of SF-36 QoL subscales stratified by BMI in the PRO cohort (n = 270).

**Figure 5:** Scatter plots of SF-36 QoL subscales stratified by BMI in the PRO cohort (n = 270).

**Figure 6:** Scatter plots of SF-36 QoL subscales stratified by BMI in the PRO cohort (n = 270).

**Figure 7:** Scatter plots of SF-36 QoL subscales stratified by BMI in the PRO cohort (n = 270).

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**References**