**Integrated personalized diabetes management (iPDM) in patients with insulin-treated T2DM: Results of the PDM-ProValue study program**

L. Heinemann¹, I. Dänschel², W. Dänschel³, D. Messinger⁴, W. Schramm⁵, I. Vesper⁶, J. Weissmann⁷, B. Kulzer⁸

¹Science Consulting in Diabetes GmbH, Düsseldorf, Germany. ²Hausarztpraxis, Lunzenau, Germany. ³MVZ am Küchwald GmbH, Chemnitz, Germany. ⁴Prometris GmbH, Mannheim, Germany. ⁵GECKO Institut, Hochschule Heilbronn, Heilbronn, Germany. ⁶Roche Diabetes Care GmbH, Mannheim, Germany. ⁷Roche Diabetes Care Deutschland GmbH, Mannheim, Germany. ⁸Forschungsinstitut Diabetes Akademie Bad Mergentheim (FIDAM), Bad Mergentheim, Germany.

**Objectives**

- Many patients with type 2 diabetes mellitus (T2DM) do not achieve their treatment goals despite an ever growing number of therapeutic options.
- Patients are often left without guidance when deciding on appropriate therapeutic actions following blood glucose measurements.
- Integrated personalized diabetes management (iPDM), an iterative 6-step structured intervention process, is supposed to support improvement of glycemic control by bringing together health care physician and patient in the therapeutic decision making.
- In the PDM-ProValue study program we assessed whether iPDM improves glycemic control and other parameters among insulin-treated patients with T2DM.

**Methods**

- The study program was conducted as 12-month, prospective, controlled, cluster-randomized studies to determine if implementation of iPDM in daily outpatient practice improves glycemic control (primary endpoint), and other clinical and patient reported outcomes (secondary endpoints).
- Patients in the control (CNL) group were treated with usual care.
- 101 medical practices (general practitioner and diabetes specialist practices) throughout Germany were randomized in the PDM arm (n=53) or in the CNL arm (n=48).
- Patient visits in the iPDM study arm followed a structured diabetes management process (Fig.1) based on demand-oriented patient education, initiation of structured self monitoring of blood glucose (SMBG), electronic documentation and software-supported visualization and analysis.
- This was followed by a joint interpretation of measurement results by HCPs and patients, a personalized treatment decision and the assessment of therapy efficacy.
- HbA1c measurements were performed by a central laboratory (Bioscientia, Ingelheim, Germany).

**Results**

- The 907 patients enrolled and evaluated in the PDM-ProValue study program were comparable at baseline (Table 1).
- After 12 months, improvement in glycemic control vs. baseline was higher for patients in the iPDM study arm (0.5%, p<0.0001) compared to those in the CNL arm (0.3%, p<0.0001; between-group change = 0.2%, p<0.05, Figure 2).
- Most of the reduction in HbA1c occurred during the first 3 months and remained stable thereafter.
- No higher incidence of hypoglycemic episodes (defined as blood glucose level <70 mg/dL) was observed in iPDM when compared to CNL.

**Conclusion**

- The outcome of the PDM-ProValue study program documents the considerable potential of personalized diabetes management.
- Structured guidance for physicians and patients based on a low-threshold digital solution represents a diagnostic measure which significantly improved glycemic control.
- These findings suggest that the combination of structured and joint evaluation of diagnostic data and therapeutic decisions provide real glycemic benefits for patients with diabetes.
- The combination of an easy-to-implement process and the integration of a software solution show the potential of iPDM to improve clinical outcomes for a large and growing group of patients with type 2 diabetes treated with insulin.

**References**