**Effects of integrated Personalized Diabetes Management: Results of the PDM-ProValue study program**

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**Objectives**

- Many people with type 2 diabetes mellitus (T2DM) do not achieve their treatment goals despite an ever growing number of diagnostic and therapeutic options. Patients are often left without guidance when deciding on appropriate therapeutic actions following blood glucose measurements.

- Bringing together the health care provider (HCP) and the patient in a shared therapeutic decision-making process and integrating digital tools for analysis and visualization of blood glucose data and statistics are supposed to improve patient outcomes.

- Both aspects are realized in the Integrated Personalized Diabetes Management (IPDM) process, an iterative, 6-step structured intervention program (Figure 1).

- The PDM-ProValue study program was designed to determine if implementing IPDM in daily practice improves glycemic control (HbA1c, primary variable) and other clinical and patient reported outcomes (secondary variables).

- Here, we report the regarding recommended changes in patients’ diabetes treatment which may account for changes in glycaemic control and other parameters.

**Results**

- 907 insulin treated patients with type 2 diabetes were enrolled in the PDM-ProValue study program and eligible for analysis. Patients in the control group and intervention group, respectively, were comparable at baseline regarding demographic and diabetes history (Table 1).

- In both groups, the largest patient share was treated with intensified conventional insulin therapy (ICT; 61.1% in iPDM vs. 61.7% in CNL), followed by basal insulin supported oral therapy (BOT; 28.6% vs. 28.5%) and, to a much lesser extent, conventional therapy (CT) and supplementary insulin therapy (Table 1).

- After 12 months, improvement in glycemic control vs. baseline (+HbA1c reduction) was higher for patients in the iPDM group (0.6%, p<0.0001) compared to those in the CNL group (0.3%, p=0.001), between-group change = 0.3%, p<0.05 (Figure 4A). Patients with a BDT regimen showed the most pronounced HbA1c reduction (Figure 4B).

- No higher incidence of hypoglycemic episodes (defined as blood glucose level <70 mg/dL) was observed in iPDM when compared to CNL.

- Throughout the study course, a significantly higher percentage of patients in the iPDM group was requested to do additional physical activity/training (40.5% compared to 20.3% in CNL). The same is true for nutrition counselling (37.0% vs. 23.3%) and recommendation for diabetes training (22.3% vs. 14.3%) (Figure 3A).

- Odds ratios (OR) of patients with recommended overall changes in medication (comprising oral antidiabetic medication and insulin dosage) was significantly higher in the iPDM group versus the CNL group starting immediately at week 3 up to month 6 (Figure 3B). In this time frame, over 50% of the patients in the iPDM group were requested to change either their OAD therapy, their insulin therapy or their therapy regimen.

- Significantly more patients in the iPDM group were asked to adapt their daily basal insulin dose compared to the CNL group early in the study course at week 3 (visit 2) and month 3 (visit 3) (Figure 3C).

- Patients in both groups were less frequently asked to adapt their daily prandial insulin dose, but still with a trend in favor of the iPDM group, reaching significance at month 12 (Figure 3D).

**Methods**

- The 12-month, prospective, controlled, cluster-randomized study program enrolled 907 eligible patients from 101 study sites (general practitioner and diabetes specialist practices) throughout Germany (1).

- Study sites were randomized in the PDM (n=53) and in the control (CNL, n=48) arm (Figure 2).

- Patients with BOT, ICT, CT or ICT therapy regimen were treated in the CNL arm with usual care, the respective treatment in the PDM arm was organized according to the IPDM process.

- The study visits were conducted at baseline (visit 1), week 3 (visit 2), and months 3 (visit 3), 6 (visit 4), 9 (visit 5) and 12 (visit 6).

- HbA1c measurements were performed by a central laboratory (Bioscientia, Tübingen, Germany).

- Treatment recommendations were analyzed to understand the nature of the intended adaptations preferred by the physicians: at each study visit, physicians were asked to provide a detailed structured description of the therapy changes for each patient covering medical as well as non-medical measures.

- Non-medical measures comprised recommendations regarding diabetes training, nutrition counseling, physical activity and polemic; medical measures comprised recommendations regarding overall therapy changes and adaptations of the insulin therapy, respectively.

**Conclusion and outlook**

- Implementation of IPDM, a structured and digitally supported approach to guide the diabetes therapy process by bringing together physicians and their patients with T2D in joint decision making, resulted in significant improvements in glycemic control.

- By providing a more systematics overview regarding diabetes data for physicians and patients, IPDM seemed to trigger timely therapeutic actions, e.g. focused education/training, which have resulted in early improvements in glycemic control.

- Patients with basal supported oral therapy particularly benefited from the IPDM approach, suggesting that improvement of glycemic control can be achieved with measures easy to implement.

- The significant increase of patients with pharmaceutical and non-pharmaceutical recommendations hints at the potential of IPDM to facilitate more focused and better informed decision making and thus to overcome clinical inertia.

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**Table 1:** PDM-ProValue study program: patient demographics and diabetes history at baseline

**Figure 4:** A: HbA1c change from baseline to study week and therapy regimen, B: HbA1c change from baseline to study week, therapy regimen, iPDM group only, p<0.0001 for all interventions compared to control. CNL: Control; iPDM: integrated personalized diabetes management, LISA: least squares mean, CI: confidence interval, OR: Odds ratio (adjusted for study, gender and considering center as cluster).