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

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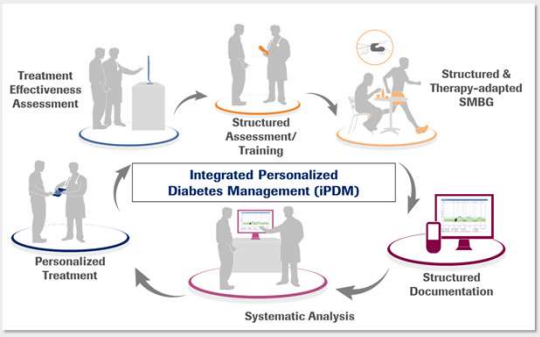
Objectives

- 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 physician (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 (primary endpoint) and other clinical and patient reported outcomes (secondary endpoints).
- Here, we report the results regarding the primary endpoint (change in HbA1c).



The iterative iPDM process starts with **1)** an initial assessment of the patient status and a demand-oriented education/training. Subsequently, **2)** blood glucose (BG) data are collected according to a structured, therapy adapted regimen, followed by **3)** electronic documentation and **4)** systematic data analysis. In step **5),** current treatment is reviewed and adapted individually when indicated and finally **6)** the treatment effectiveness is assessed at the patient's next visit. The process is then run through again.

Figure 1: *The iPDM-process*

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 iPDM arm (n=53) and in the control (CNL, n=48) arm (**Figure 2**).
- Patients with BOT, SIT, CT or ICT therapy regimen were treated in the CNL arm with usual care; the respective treatment in the iPDM 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, Ingelheim, Germany).

Results

- The 907 eligible patients 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 3**).
- Most of the reduction in HbA1c occurred after 3 months and remained nearly stable thereafter.
- No higher incidence of hypoglycemic episodes (defined as blood glucose level <70 mg/dL) was observed in iPDM when compared to CNL.

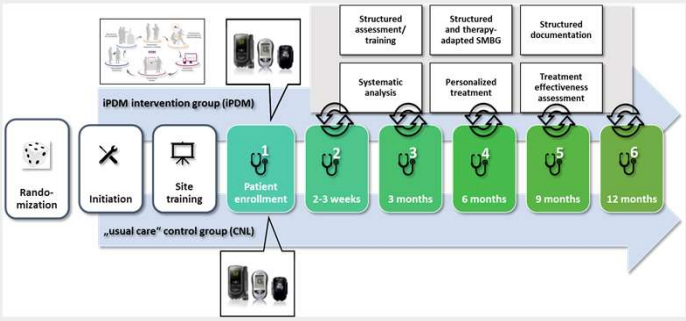
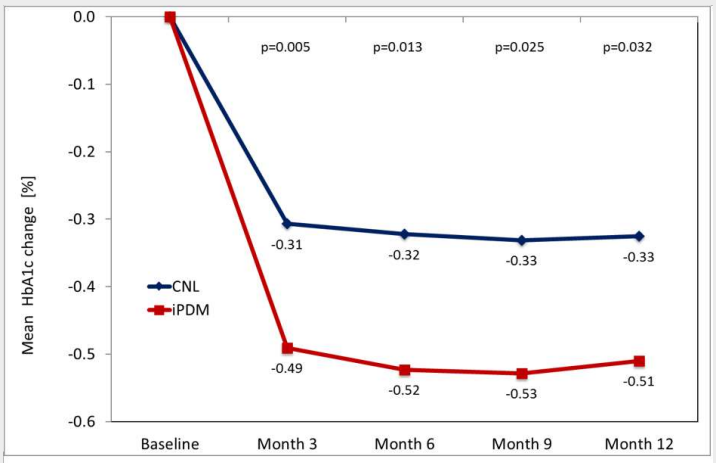


Figure 2: *PDM-ProValue study flow*

	iPDM n=440	CNL n=467
Male, n (%)	266 (60.5%)	261 (55.9%)
Age (years), mean (SD)	64.5 (10.9)	64.9 (10.0)
Current smoker, n (%)	66 (15.0%)	63 (13.5%)
BMI (kg/m^2), mean (SD)	33.8 (6.1)	34.0 (6.1)
Time since diagnosis (years), mean (SD)	14.4 (8.7)	14.3 (7.8)
Baseline HbA1c (%), mean (SD)	8.5 (1.1)	8.4 (1.0)
Diabetes Regimen, n (%)		
Basal supported oral therapy (BOT)	126 (28.6%)	133 (28.5%)
Supplementary insulin therapy (SIT)	12 (2.7%)	15 (3.2%)
Conventional therapy (CT)	33 (7.5%)	31 (6.6%)
Intensified conventional therapy (ICT)	269 (61.1%)	288 (61.7%)
SMBG frequency per week, n (SD)	20.3 (10.9)	21.4 (11.2)
Time since start of insulin therapy (years), mean (SD)	7.1 (6.6)	7.3 (6.5)
Patients with diabetes complications, n (%)	317 (72.0%)	329 (70.4%)

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



Between-group difference (LSM)	0.18	0.20	0.20	0.19
95% CI (of between-group difference)	0.05 - 0.31	0.04 - 0.36	0.02 - 0.37	0.02 – 0.35

Figure 3: *HbA1c change from baseline*
CNL: Control, iPDM: integrated personalized diabetes management, LSM: least squares mean, CI: confidence interval

Conclusion and outlook

- The outcome of the PDM-ProValue study program documents the considerable potential of integrated, personalized diabetes management.
- Providing a process which includes structured guidance for physicians and patients together with a low-threshold digital solution resulted in significantly improved glycemic control.
- The combination of an easy-to-implement approach 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 and may help to overcome clinical inertia
- Further expanding the process with adequate digital tools and opening it up for additional, sophisticated solutions for coaching or education can be key to addressing the needs of all people with diabetes.

1) Kulzer B. et al 2015): Integrated Personalized Diabetes Management (PDM): Design of the ProValue Studies: Prospective, Cluster-Randomized, Controlled, Intervention Trials for Evaluation of the Effectiveness and Benefit of PDM in Patients With Insulin-Treated Type 2 Diabetes. J Diabetes Sci Technol. 2016 May 3;10(3):772-81

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