

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

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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 program, 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 induces improvements in glycemic control and other parameters among insulin-treated patients with T2DM.

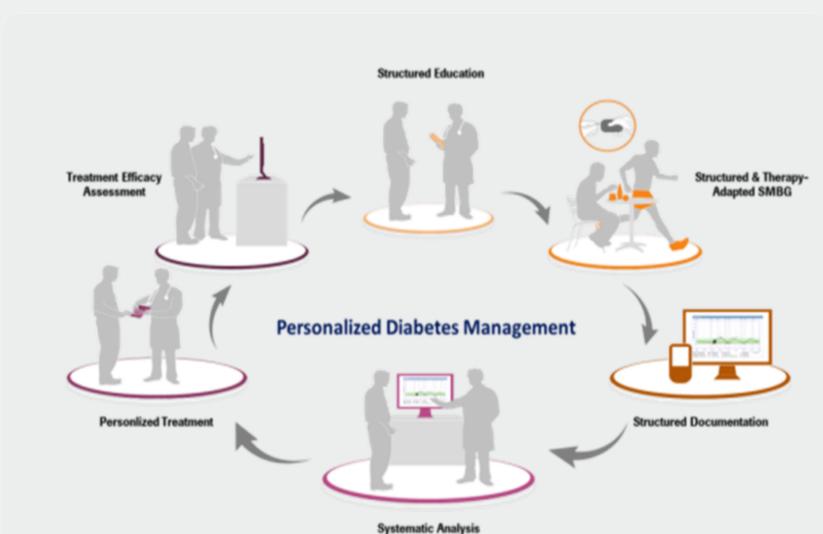


Figure 1: The iPDM-Process

	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), n (SD)	33.8 (6.1)	34.0 (6.1)
Time since diagnosis (years), n (SD)	14.4 (8.7)	14.3 (7.8)
Baseline HbA1c, % (SD)	8.5 (1.1)	8.4 (1.0)
Diabetes Regimen, n (%)		
Basal supported oral therapy (BOT)	68 (26.0%)	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, years (SD)	7.1 (6.6)	7.3 (6.5)
Diabetes complications, n (%)	317 (72.0%)	329 (70.4%)

Table 1: Baseline demographics

Methods

- The study program was conducted as 12-month, prospective, controlled, cluster-randomized studies to determine if implementation of iPDM in daily 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) and in the UC arm (n=48).
- Visits of the patients in the iPDM study arm followed a structured diabetes management process based on demand-oriented patient education, the initiation of structured self monitoring of blood glucose (SMBG), the electronic documentation and software-supported visualization and analysis.
- This was followed by a joint interpretation of measurement results by HCP and patients and an assessment of the therapy efficacy (Fig.1).
- HbA1c measurements were performed by a central laboratory (Bioscientia, Ingelheim, Germany).

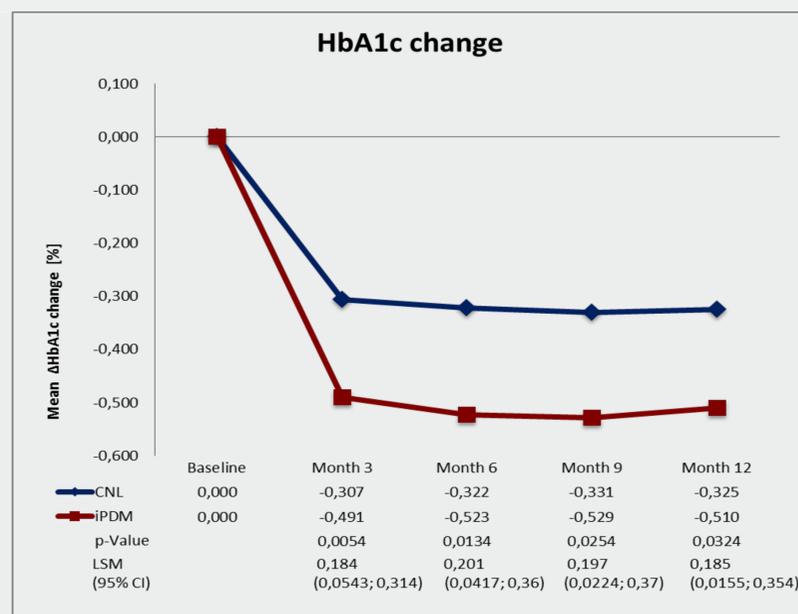


Figure 2: HbA1c change from baseline

CNL: Control, iPDM: integrated personalized diabetes management, LSM: least squares mean, CI: confidence interval

Results

- The 907 patients enrolled 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 after 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 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.

References

Kulzer et al (2016): 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. 10(3):772-81