# **IMPACT OF A DIGITAL THERAPEUTIC ON INSULIN SELF-MANAGEMENT**

Authors: Yifat Hershcovitz Ph.D., Sharon Dar and Omar Manejwala M.D.

DarioHealth Corp

## Introduction

Effective therapy reduces disease burden and economic impact in Diabetes Mellitus<sup>1</sup>. Insulin is the most effective antihyperglycemic treatment and is the preferred initial formulation in patients with type 2 diabetes<sup>2</sup>. Adherence to self-monitoring and the avoidance of hypoglycemia are critically important for patients using insulin. Dario, a digital therapeutic platform for diabetes management, may assist patient titration of basal insulin to achieve optimal outcomes.

## **Method**

A retrospective study was performed on a population of 285 active Dario's users (85% with type 2) under insulin therapy, who measured with Dario for at least three months and logged basal insulin usage. The users measured at least five blood glucose measurements per month and logged their basal insulin in their first three months. Data on glycemic endpoints such as fasting blood glucose (FBG) and insulin injections were extracted. The study population included two groups, one included 112 users whose starting average blood glucose was >180 mg/dL. Among this group the average age was 50±20.8. The second group included 173 users whose starting average blood glucose was <180 mg/dL with average age 54±19.9. First month measuring on platform was used as study baseline.

## **Results**

In the group of 112 users starting with blood glucose average above 180 mg/dL:

- The average amount of basal insulin per injection increased by six units after three months (45±36 vs. 39±31) (Table 1).
- FBG was significantly reduced (9%) after three months vs. baseline(186±57 vs. 204±62) (P<0.002) without change in average hypoglycemia events ratio (<70 mg/dL).
- Average blood glucose was significantly reduced (9%) after three months (207±49 vs. 228±44) (P<0.001) (Figure 1).

• 15% of the users reduced their FBG average to less than 126 mg/dL. In the sub-group of 173 users who started at average blood glucose below 180 mg/dL, basal insulin and FBG levels remained stable for the following three months (Table1) and 49% reduced the average to less than 126 mg/dL.



**Figure 1:** Blood glucose average, fasting blood glucose average and basal level of Insulin over three months.

### Sources:

report on diabetes. Geneva, 2016.

1. World Health Organization. Global 2. Marco Castellana et at "Efficacy and safety of patient-led Versus physician-led titration of basal insulin in patients with uncontrolled type 2 diabetes: a meta-analysis of randomized controlled trials" BMJ Open Diab Res Care 2020.

**3.** Ji Chun et al. "Insulin Initiation and Titration in Patients With Type 2 Diabetes" SPECTRUM.DIÁBETESJOURNALS.ORG Vol. 32

## **Discussion**

With an increasing number of insulin treatment options available, diabetes management is moving away from a "one size-fits-all" approach toward individualized treatment regimens based on patient needs<sup>3</sup>. Appropriate dose titration is crucial to achieve glycemic targets. In clinical practice, physicians and persons with diabetes often do not adhere to achieve optimal titration as they perceive these to be very cumbersome<sup>4</sup>. A digital therapeutic platform for diabetes management could create an immediate feedback mechanism prompting patients to adhere to their treatment recommendations when FBG is the decision-making criterion. A target <126mg/dL is usually selected for safety considerations. ADA classifications consider FBG<126 mg/dL to either prediabetes or normal. Using the digital platform, we see users who started with high risk levels reduced their average blood glucose and particularly fasting levels, partly to less than 126 mg/dL. Previous studies had demonstrated that the significant change during insulin management occurs during the third month vs. baseline supporting the results observed in the study<sup>5</sup>.

## **Conclusion**

This observational study demonstrates the potential benefit of a digital diabetes management platform in the self-management required from insulin treated users, incorporating its use on a daily base, and sustaining behavioral change.

Measure	Group	Month1	Month2	Month3
Average fasting blood glucose (mg/dl)	N=112; ≥180mg/dl	204±62	195±55	186±57
	N=173; <180mg/dl	134±26	131±30	133±33
Average blood glucose (mg/dl)	N=112; ≥180mg/dl	228±44	212±44	207±49
	N=173; <180mg/dl	146±20	146±26	149±30
Average Basal Insulin (units)	N=112; ≥180mg/dl	39±31	42±34	45±36
	N=173; <180mg/dl	35±28	36±28	36±28

**4.** Sunil M. Jain et al "Best Practices and Tools for Titrating Basal Insulins: Expert Opinion from an Indian Panel via the Modified Delphi Consensus Method". Diabetes Ther (2020) 11:621-632

**5.** Yong Mong Bee et at. "A Smartphone Application to Deliver a Treat-to-Target Insulin Titration Algorithm in Insulin-Naive Patients With Type 2 Diabetes" Diabetes Care 2016;39





MK-0295 RevA