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Impact of Digital Diabetes Solution on Glycemic Control in Adults With Type 2 Diabetes Mellitus in the United States: **A Retrospective Cohort Study** Nita Thingalaya,¹ David Kerr,² Praveen Potukuchi,¹ Laura Wilson,¹ Keni C.S. Lee,³ Edward Jonathan Han-Burgess,⁴ Alison Edwards,⁵ Xinyan Yu,⁵ Adee Kennedy,¹ Felix Lee¹

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INTRODUCTION

- Diabetes, a chronic condition that requires continuous management, has been estimated to affect 37.3 million individuals in the United States.¹
- A reduction in glycated hemoglobin (HbA1c) of ~1% is associated with decreased risk of diabetes-related complications.²
- Digital healthcare technologies allow for personalized intervention and have been developed to improve diabetes care management.^{3,4}
- Digital healthcare technology can reduce HbA1c levels in patients with type 2 diabetes mellitus (T2DM) compared with usual care.⁴
- Dario Diabetes Solution (DDS) is a digital health application for diabetes management.
- DDS combines a blood glucose meter and a mobile application, allowing patients to track blood glucose levels in real-time.

OBJECTIVE

 To evaluate effectiveness of DDS on HbA1c reduction in DDS users compared with a matched non-user cohort

METHODS

 In this retrospective cohort study, the patient selection window was January 2017 to October 2021 (Figure 1).

Figure 1: Study timeline DDS Users (n=568) DDS Non-Users (n=1699) Adults with T2DM, with baseline Adults with T2DM, with baseline HbA1c ≥7% who did not use HbA1c ≥7% who used DDS DDS but received usual care Baseline Period: Follow-Up Period: 6 months* look forward from index 1 year look back from index October 2021 January 2017 Index Event DDS users: registration date DDS non-users: 1st claim date in quarter *HbA1c values were captured at 6 months (180 + 60 days). DDS, Dario Diabetes Solution; HbA1c, glycated hemoglobin; T2DM, type 2 diabetes mellitus.

 User and non-user cohorts were sequentially matched 1:3 using exact and propensity score matching (Figures 2 and 3).

EXACT MATCH



Quarter of index date falls

PROPENSITY SCORE MATCH



Age

CCI, Charlson Comorbidity Index; DDS, Dario Diabetes Solution; HbA1c, glycated hemoglobin.



- Inclusion criteria

- +420 days)
- Excluded were patients with continuous glucose monitoring before and within 420 days after app registration.
- Primary endpoint was change in HbA1c from baseline to 6 months.
- Subgroup analyses
- Patients stratified by baseline HbA1c of >7.5%, >8%, and >9%
- Difference-in-difference results were reported using least squares (LS) means from linear models.



Figure 3: Mirrored histogram of propensity scores

 Patients ≥18 years old with T2DM who used DDS or received usual care Patients receiving ≥1 diabetes medication (oral or injectable) before index date Patients with HbA1c ≥7% during baseline (index -365 days to index +30 days) Patients with ≥1 HbA1c measurement during follow-up (index +31 days to index

Patients with ≥1% drop in HbA1c compared with baseline

RESULTS

• For the total 2267 patients, mean ± SD age was 57.5±11.3 years, and baseline HbA1c was 9.14±1.83%; cohorts were well matched (Table 1, Figure 4).

Table 1: Demographics and baseline cha

| Characteristics | DDS User Cohort n=568 | DDS Non-user Cohort n=1699 | Standardized Mean Difference [†] | | | |
|--|-----------------------------|----------------------------------|---|--|--|--|
| Mean ± SD age, years | 57.3±10.5 | 57.6±11.6 | -0.027 | | | |
| Female, n (%) | 262 (46.1) | 784 (46.1) | -0.0004 | | | |
| Race, n (%) | | | | | | |
| African American | 55 (9.7) | 173 (10.2) | -0.017 | | | |
| Asian | 8 (1.4) | 22 (1.3) | 0.010 | | | |
| Hispanic | 66 (11.6) | 202 (11.9) | -0.008 | | | |
| White | 316 (55.6) | 933 (54.9) | 0.014 | | | |
| Mean ± SD HbA1c, % | 9.14±1.78 | 9.13±1.85 | 0.006 | | | |
| Antidiabetic medications, n (%) | | | | | | |
| Any combination/other injectable only | 245 (43.1) | 734 (43.2) | -0.001 | | | |
| Insulin only | 34 (6.0) | 101 (5.9) | 0.002 | | | |
| Oral antidiabetic medications | 289 (50.9) | 864 (50.9) | 0.0005 | | | |
| *For all characteristics, the difference between DDS users and non-users was not statistically significant | | | | | | |

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[†]Standardized mean difference threshold was 0.1.

DDS, Dario Diabetes Solution; HbA1c, glycated hemoglobin; T2DM, type 2 diabetes mellitus.

Figure 4: Geography & payment type Matched DDS Users (n=568) Northeas 4.8% Midwes 12.2% Southeast 32.6% Other Territories Commercial Medicare 17.8% Other 6.7 Medicaid* 4.9% 0 10 20 30 40 50 60 70 80 *Medicaid/Managed Medicaid. DDS, Dario Diabetes Solution.

- At 6 months, LS mean difference between DDS users and non-users was -0.23% (Figure 5).
- DDS users achieved significantly greater reduction in HbA1c compared with non-users (*P*=0.004).

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- In subgroup analysis, DDS users achieved greater reduction in HbA1c across different baseline HbA1c levels compared with non-users (P<0.002; Figure 5).
- For patients with baseline HbA1c >9%, the standard Healthcare Effectiveness Data and Information Set (HEDIS) performance measure, mean difference between groups was -0.47%.





*Change from baseline (generalized linear model mean). DDS, Dario Diabetes Solution; HbA1c, glycated hemoglobin. Bars represent mean HbÁ1c.

Figure 7: Patients with ≥1% reduction in HbA1c at 6 months compared with baseline



DDS, Dario Diabetes Solution; HbA1c, glycated hemoglobin. Bars represent percentage of patients. Error bars represent 95% CI.



- At 6 months, DDS user subgroups stratified by baseline HbA1c levels achieved significant reduction in HbA1c compared with baseline (P<0.0001 for all; Figure 6).
- At 6 months, an HbA1c drop ≥1% from baseline was achieved by 10.2% more DDS users vs non-users (P<0.001; Figure 7).

CONCLUSIONS

- In this retrospective cohort study, adults with uncontrolled T2DM using DDS had better glycemic outcomes at 6 months compared with non-users.
- At 6 months, DDS users achieved a significantly greater reduction in HbA1c compared with non-users (-0.23%; *P*=0.004).
- For patients with higher baseline HbA1c (HEDIS endpoint >9%), DDS users achieved greater HbA1c reduction compared with non-users (-0.47%; P=0.0016).
- DDS user subgroups stratified by baseline HbA1c levels achieved significant reduction in HbA1c compared with baseline (*P*<0.0001).
- A significantly greater proportion of DDS users achieved HbA1c reduction $\geq 1\%$ compared with non-users (P<0.001).
- Given the retrospective study design, residual confounding differences may exist between groups; however, the study overall had a robust methodology of exact and propensity score matching.

References

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Disclosures

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