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Impact of Personal Health Records on Diabetes Management: A Propensity Score Matching Study

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Abstract: Background: Effective self-management is crucial in diabetes care. This study investigates the impact of Personal Health Records (PHR) on diabetes management and person self-management behaviors. Methods: Retrospective cohort study was conducted involving individuals with diabetes using insulin and prescribed FreeStyle Libre®. Participants were categorized into PHR users and non-users. Key metrics such as HbA1c, Time in Range (TIR), Time above Range (TAR), and body weight were analyzed. Results: Among 212 intermittently scanned continuous glucose monitoring (isCGM) users, 25 individuals used PHR. Comparing 21 individuals using a PHR with 42 matched controls, the TIR significantly increased (ΔTIR 17.2% vs. 1.90%, $p = 0.020$), and HbA1c levels showed a greater decrease (ΔHbA1c −0.83% vs. −0.22%, $p = 0.023$). A significant reduction was also observed in TAR among PHR users (ΔTAR −17.6% vs. −1.63%, $p = 0.017$). There were no significant changes in body weight (ΔBW −0.51 kg vs. −1.60 kg, $p = 0.578$). Conclusions: PHR systems demonstrate potential in improving diabetes management by enhancing self-management practices and glycemic control. Although the sample size of PHR users was relatively low, PHR should be more widely used. The study underscores the need for further research on PHR's long-term impact and its applicability in diverse diabetic populations.

Keywords: self-management; PHR; isCGM

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1. Introduction

In diabetes care, self-management, which includes lifestyle improvement and self-monitoring of blood glucose levels, is essential [1,2]. The ultimate therapeutic goal for diabetes is to achieve an independent, healthy lifespan comparable to that of individuals without diabetes [3]. To accomplish this, a fundamental focus on education emphasizing lifestyle improvement is necessary, regardless of the treatment program [1,2]. This should be complemented by pharmacological treatment as needed, with methods and goals individualized based on the person's specific needs.

Being 'person-centered' involves respecting the individual lifestyles, values, and needs of persons and tailoring approaches accordingly [4]. This approach also acknowledges that persons' values can influence the determination of the clinical path, including lifestyle choices and medication selection [4]. While dietary therapy, exercise, and person education are fundamental in the treatment of diabetes, in the person-centered approach, the optimal glycemic target is determined based on factors such as the person's condition, risks associated with treatment medications, and the presence of complications. From the perspective of person-centered care, it is important for healthcare professionals involved in diabetes

management to understand person' lifestyles and provide appropriate advice within the constraints of limited consultation time, which can be challenging.

The management for diabetes has traditionally employed a team-based approach, to achieve glycemic control (GC) targets, including HbA1c and Time in Range (TIR). A model anticipated to be enhanced by the integration of online care even before the COVID-19 pandemic. Thea pandemic, however, has necessitated a shift in this approach to accommodate evolving lifestyles [5–7]. Diabetes technologies are as important as, or more important than, medications in preventing long-term disabling complications. It has proven that the home monitoring of vital parameters and use of telemedicine can bring down the long-term vascular complications of diabetes and thereby reduce the overall cost and improve the quality of life of patients [8]. The intervention with a smartphone app and intermittently scanned continuous glucose monitoring (isCGM) increased GC accompanied by decreased carbohydrate intake and weight loss [9].

'Health2sync', a Personal Health Record (PHR) system developed in Taiwan, has been pivotal in the digitalization of diabetes care. This system supports online, team-based healthcare, involving various healthcare professionals, and is designed for managing chronic conditions like hypertension and diabetes. With approximately over 1,200,000 users globally, mainly in Taiwan, and significant usage in Japan, it stands out as a leading PHR system in Asia. The COVID-19 pandemic has further highlighted the need for adaptable healthcare practices, making systems like Health2sync® more relevant. In addition to importing data from smart insulin pens and integrating FreeStyle Libre®Link data, Health2sync® enables users to upload meal photos. This functionality aids self-management and allows healthcare professionals and family members to participate actively in care. The system's ability to aggregate data related to lifestyle factors such as diet and exercise enhances the provision of timely, accurate healthcare advice. For users, it offers detailed monitoring of insulin administration, which is crucial for error prevention and adherence, particularly among the older people. The system also includes alert mechanisms for significant fluctuations in blood sugar levels and data biases, enhancing patient safety. Healthcare providers with access to Health2sync® can view comprehensive patient data, facilitating better-informed medical decisions.

2. Materials and Methods

2.1. Ethics

The KAMOGAWA cohort study included diabetic patients from several outpatient clinics, including Kyoto Prefectural University of Medicine (KPUM, Kyoto, Japan) and Kameoka Municipal Hospital (Kameoka, Japan), and received approval from the Research Ethics Committee of Kyoto Prefectural University of Medicine (approval number: ERB-C-1876, 10 November 2020), and conducted an opt-out procedure as a cohort study that complied with the principles of the Declaration of Helsinki and did not require informed consent. In this study, outpatients at Kyoto Prefectural University of Medicine (KPUM, Kyoto, Japan) and Kameoka Municipal Hospital (Kameoka, Japan) were included in the study.

2.2. Patients, Study Design, and Data Collection

The study aims to examine the differences in blood glucose management indicators between individuals who use a Personal Health Record (PHR) and those who do not, thereby elucidating the impact of integrating PHR into diabetes care. Employing a retrospective cohort design, the study collected anonymized medical data. Data encompassed lifestyle factors, medications, laboratory data, and Continuous Glucose Monitoring (CGM) outcome metrics. These metrics included Time in Range (TIR), derived from persons undergoing insulin treatment with isCGM. Lifestyle-related data, such as cigarette and alcohol consumption and exercise habits and biochemical data were extracted from electronic medical records (EMR). CGM outcome metrics were accessed via LibreView, allowing outperson staff to review data scanned by persons from the FreeStyle Libre® (Abbott) using LibreLink.

2.3. Exclusion Criteria

We set exclusion criteria as follows: participants who were lost to follow-up, transferred to another medical institution, or moved to a different department within the same hospital, or discontinued use of Health2sync® app. Cases that had not used Health2sync® app for over a week or had uninstalled were defined as discontinued use of Health2sync® app.

We checked smartphone of each PHR users to see their application usage during outpatient counseling and confirmed that there was no discontinuation of use.

2.4. Group Settings

Standard Diabetes Care: Both cohorts received standard diabetes care in accordance with established clinical guidelines.

PHR Group: Participants in this group were provided with written instructions for installing the application, and additional assistance was offered as required.

2.5. Application Features

The Health2sync® app is a personal health record that can be used on smartphones (Figure A1). This app analyzes user-recorded data such as blood glucose levels, blood pressure, weight, medication status, diet, and exercise, creating opportunities for users to reflect on their behaviors and thereby supporting self-health management.

Medications are recorded automatically or manually. The use of devices such as NovoPen Echo®, SoloSmart® or Mallya® automatically records the type and volume of insulin used and the time of self-injection. Meals can be recorded using the smartphone's camera function to record mealtimes and photos of meals. And with connecting with Apple Healthcare®, Fitbit® and GoogleFit® the number of steps and other metrics are automatically recorded.

PHR systems are used by over 400,000 people in Japan. Users can share their data with a connected healthcare provider through the Patient Management Platform.

2.6. Primary and Secondary Outcomes

The primary outcomes of the study were the changes in Hemoglobin A1c (HbA1c) and Time in Range (TIR). Secondary outcome were the changes in Time above Range (TAR), Time below Range (TBR), and Body weight (BW) at six months following the commencement of the follow-up period.

The Japan Society for the study of Obesity (JASSO) defines obesity as a BMI of over 25 kg/m^2. Additionally, a weight loss of 3% within 3 to 6 months is considered necessary for the correction of obesity. In this context, achieving a BMI below 25 or a weight loss of 3% or more at the end of the follow-up period is regarded as a successful reduction. We conducted multivariate analysis to evaluate the factors related to the rate of change in body weight (ΔBW%) in PHR group, then we add ΔBW% (PHR) to secondary outcomes.

Covariates such as age, gender, type of diabetes, Body Mass Index (BMI), initial HbA1c levels, and the method of insulin administration were considered. Propensity score matching, adjusting for these covariates, was performed to enhance the comparability of the groups.

2.7. Propensity Score Matching

To remove selection bias of app users, propensity score matching was performed. Sex, baseline age, initial HbA1c level, BMI, type of diabetes, and insulin administration methods were selected, and a propensity score for PHR use was calculated using these factors. Propensity score matching was performed and propensity score-matched cohorts (1:2 matching ratio) were built. The matching was performed using the nearest-neighbor matching method with a caliper width set at 0.0146. This approach ensured that the propensity scores of the Control group were closely aligned with those of the Application group.

2.8. Statistical Analyses

Data analysis was conducted using JMP version 13.2 software (SAS Institute, Cary, NC, USA) and EZR. Results are presented as medians with standard deviation (SD) and frequencies with percentage. The differences in the changes observed during the follow-up period between the two groups were evaluated using the Wilcoxon rank-sum test. In this study, differences yielding a p-value of less than 0.05 were considered statistically significant.

To remove selection bias of app users, propensity score matching was performed and propensity score-matched cohorts (1:2 matching ratio) were built. This approach ensured that the propensity scores of the Control group were closely aligned with those of the Application group. The propensity scores were calculated considering variables such as sex, baseline age, initial HbA1c level, BMI, type of diabetes, insulin administration methods, and month of study commencement. Matching was performed using the nearest-neighbor matching method with a caliper width set at 0.0146.

3. Results

3.1. Study Characteristics

A total of 223 persons who were receiving insulin therapy and had been prescribed the FreeStyle Libre® were included in this study. As shown in Figure 1, participants were categorized as PHR users if they agreed to use the Personal Health Record (PHR) system, and as non-PHR users if they did not. Exclusions from the study included participants who were lost to follow-up (n = 2), transferred to another medical institution (n = 8), or moved to a different department within the same hospital (n = 1). The 11 individuals excluded were all from the non-PHR user group, whereas all PHR users continued with their PHR use. From 1 February 2022, to 31 January 2023, all participants were encouraged to use PHR by demonstrating its utility. The follow-up period was set at 6 months from the initiation of PHR use for PHR users. Similarly, non-PHR users were observed for 6 months starting from the time they were suggested to use PHR. No specific functionalities of the PHR system were mandated for use during the study period. Table A1 displays the baseline characteristics of all participants in the current study. We enrolled 212 persons, of whom 124 (58.5%) were male, and 136 had been diagnosed with type 2 diabetes. The median age of the study participants was 63.6 ± 14.9 years, and the median Body Mass Index (BMI) was 23.6 ± 6.10 kg/m^2. Of the participants, 17% were undergoing basal supported oral therapy, while 77.4% were receiving basal-bolus treatment. Smart insulin devices, such as NovoPen® and NovoPen Echo Plus®, which can be integrated with a smartphone through an app, were more commonly chosen by PHR users. A significant trend towards the use of smart insulin devices was observed, likely due to their smartphone connectivity capabilities. The median HbA1c was 7.86 ± 1.30%, and the median TIR was 60.9 ± 21.9. Number of hypoglycemia (blood glucose level < 54 mg/dL) per 2 weeks was 5.12 ± 8.15, showing less frequency in PHR group (4.08 ± 8.40). No significant differences were observed between the two groups in terms of smoking history and alcohol consumption history. However, a significant difference in exercise habits was noted in the PHR users.

3.2. Changes in Glycemic Outcomes in All Participants

In PHR group, the TIR significantly extended (ΔTIR 17.3 ± 27.2 vs. −1.10 ± 17.8, p = 0.002), and HbA1c decreased (ΔA1c −0.89 ± 1.34 vs. −0.22 ± 1.02, p = 0.004). A significant reduction was also observed in the Time Above Range (TAR) in the PHR group (ΔTAR −17.8 ± 27.4 vs. −1.80 ± 18.2). An increase in total daily dose (TDD) was noted in the PHR group (4.40 ± 4.36 vs. 0.50 ± 0.51, p = 0.017) (refer to Table A2). Change in BW was not significant in PHR group (ΔBW −0.19 vs. −0.27, p = 0.957). Moreover, the number of hypoglycemia per 2 weeks did not show significant decrease in PHR group (−0.16 vs. 0.65, p = 0.453).

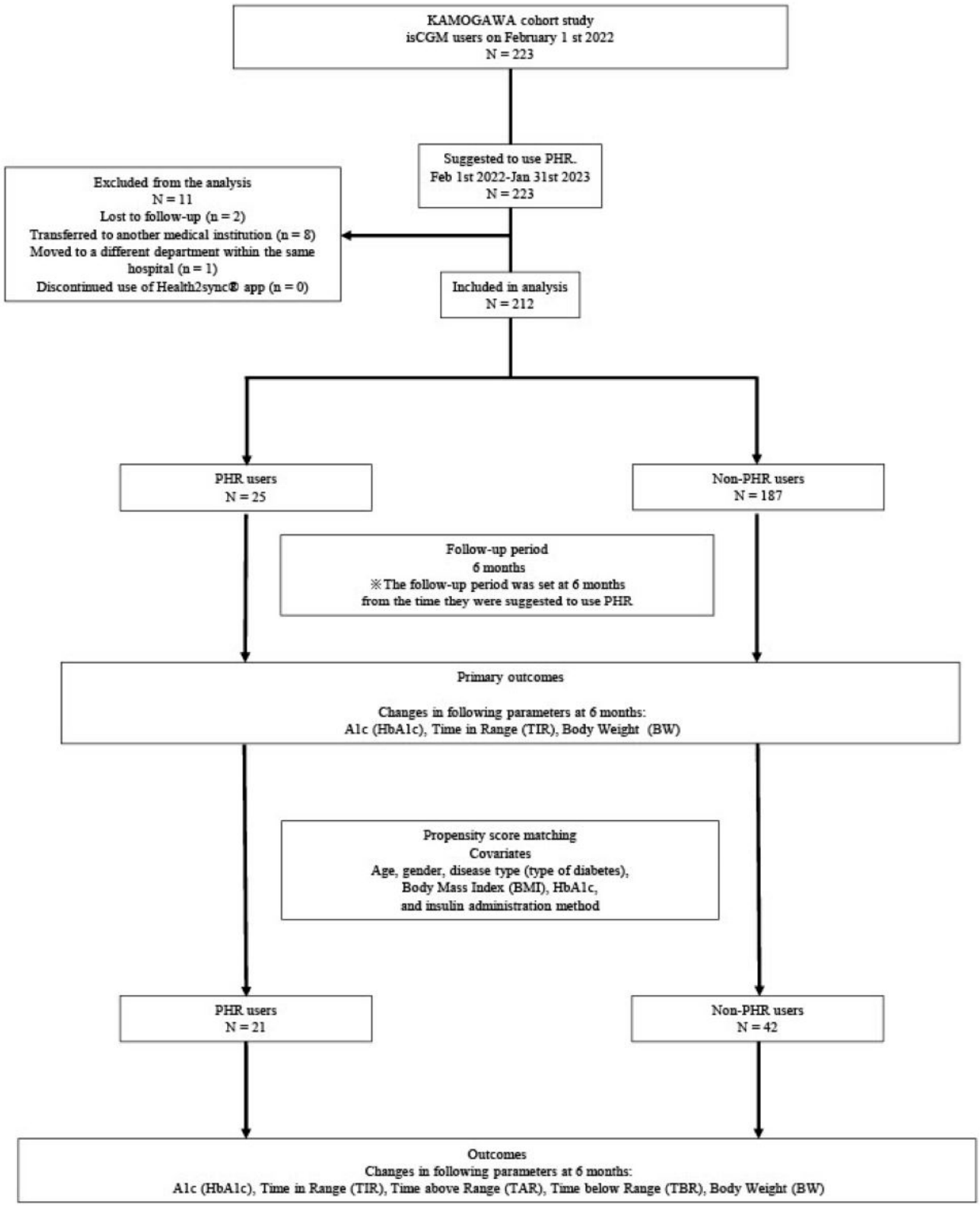

Figure 1. This figure demonstrates study design. Participants were categorized as PHR users if they agreed to use the Personal Health Record (PHR) system, and as non-PHR users if they did not. Exclusions from the study included participants who were lost to follow-up (n = 2), transferred to another medical institution (n = 8), or moved to a different department within the same hospital (n = 1). Changes in HbA1c, Time in Range (TIR), Time above Range (TAR), Time below Range (TBR) and body weight (BW) were analyzed. The follow-u *p* period was 6 months.

3.3. Propensity Score Matching

In this study, we performed propensity score matching considering age, gender, disease type (type of diabetes), BMI, HbA1c, and insulin administration method as covariates. A total of 21 pairs were formed for the comparison of glycemic management, consisting of 21 individuals using a PHR system and 42 individuals not using PHR. Table 1 shows the baseline characters of these pairs. Among PHR users, the TIR significantly increased (ΔTIR 17.2 vs. 1.90, $p = 0.020$), and HbA1c levels showed a greater decrease (ΔHbA1c −0.83 vs. −0.22, $p = 0.023$). A significant reduction was also observed in TAR among PHR users (ΔTAR −17.6 vs. −1.63, $p = 0.017$). There were no significant changes in BW (ΔBW −0.51 vs. −1.60, $p = 0.578$) (refer to Table 2).

Table 1. Baseline characters of matched 21 pairs (1:2).

	Total	**PHR (+)**	**PHR (−)**	***p* Value**
	N = 63	**N = 21**	**N = 42**	
Age (years)	58 ± 14.7	58 ± 13.3	58 ± 15.5	0.907
Sex (Female)	14 (22.2)	6 (28.6)	8 (19.0)	0.391
BMI (kg/m^2)	24.6 ± 6.28	25.1 ± 6.47	24.4 ± 6.25	0.625
Type (T2DM)	41 (65.1)	15 (71.4)	26 (61.9)	0.455
DM medication (Insulin)				0.391
Basal supported oral therapy	14 (22.2)	6 (28.6)	8 (19.1)	
Basal-bolus treatment	49 (77.8)	15 (71.4)	34 (81.0)	
CSII/SAP	0	0	7 (3.70)	
Total daily dose (TDD)	29.0 ± 19.1	24.0 ± 17.9	31.6 ± 19.4	0.085
Number of smart insulin user	12	10	2	<0.001
Glucose ave	176.9 ± 52.2	184.4 ± 58.2	173.1 ± 49.2	0.662
HbA1c (%)	7.94 ± 1.36	8.20 ± 1.64	7.80 ± 1.18	0.620
TIR (%)	56.7 ± 22.4	54.5 ± 28.7	57.8 ± 18.8	0.903
TAR (%)	40.2 ± 24.6	44.0 ± 30.0	38.3 ± 21.6	0.720
TBR (%)	3.13 ± 6.08	1.50 ± 3.46	3.95 ± 6.93	0.062
MAGEave	124.0 ± 38.4	116.5 ± 30.0	127.8 ± 41.8	0.322
CV	33.1 ± 8.00	29.3 ± 5.74	33.9 ± 8.75	0.006
Number of Hypoglycemia per 2 weeks	4.87 ± 8.15	4.06 ± 8.40	5.28 ± 8.02	0.070
Cigarrete				0.117
Never smoker	38 (60.3)	11 (52.4)	27 (64.3)	
Ex-smoker	17 (27.0)	8 (38.1)	9 (21.4)	
Current smoker	8 (12.7)	1 (4.76)	7 (16.7)	
Alcohol	26 (41.3)	10 (47.6)	16 (38.1)	0.246
Exercise				<0.001
Regulary	16 (25.4)	2 (9.5)	14 (33.3)	
Rare	32 (50.8)	18 (85.7)	14 (33.3)	
Receiving Medical Nutritional therapy	11 (17.5)	5 (23.8)	6 (14.3)	0.348

This table displays the baseline characteristics of 63 matched 21 pairs.

Table 2. Changes in glycemic outcomes after conducting propensity score matching.

	Total	**PHR (+)**	**PHR (−)**	***p* Value**
	N = 63	**N = 21**	**N = 42**	
ΔA1c	−0.42 ± 1.43	−0.83 ± 1.40	−0.22 ± 1.44	0.023
ΔTIR	6.91 ± 24.3	17.2 ± 27.6	1.76 ± 21.0	0.016
ΔTAR	−3.7 ± 24.8	−17.6 ± 27.9	−1.42 ± 21.4	0.013
ΔTBR	−0.05 ± 2.70	0.42 ± 1.71	−0.29 ± 3.06	0.324
ΔBW	−1.23 ± 7.20	−0.51 ± 1.96	−1.60 ± 8.71	0.578

This table shows the baseline characters of these pairs. Among PHR users, the TIR significantly increased (ΔTIR 17.2 vs. 1.90, $p = 0.020$), and HbA1c levels showed a greater decrease (ΔHbA1c −0.83 vs. −0.22, $p = 0.023$). A significant reduction was also observed in TAR among PHR users (ΔTAR −17.6 vs. −1.63, $p = 0.017$). There were no significant changes in BW (ΔBW −0.51 vs. −1.60, $p = 0.578$).

Before the intervention in PHR group, 11 people had BMI of over 25 kg/m^2, however, only one of them achieved less than BMI 25 kg/m^2 at the end of follow-up period, showing 8.4% decrease in body weight. From the perspective of the rate of change in body weight (ΔBW%), 3 individuals who had BMI of over 25 kg/m^2 showed certain weight loss: 3.50%, 4.40%, 8.40%, respectively. In the multivariate analysis (refer to Table 3), reception of medical nutritional treatment (MNT) ($p = 0.029$, $\beta = -0.73$), smoking cessation ($p = 0.039$, $\beta = 0.58$), non or occasional drinking ($p = 0.004$, $\beta = 1.08$), habit of taking exercise ($p = 0.032$, $\beta = -0.78$) were independently associated with ΔBW%. Characteristics, changes in biochemical data, body weight, BMI, and CGM metrics of the Individuals who had BMI of over 25 kg/m^2 before intervention can be seen in Table A4.

Table 3. Multivariate analysis in PHR group; factors related to the rate of change in BW (ΔBW%).

	Standardized Regression Coefficient	*p*
MNT (+/−)	−0.73	0.029
ΔA1c	−0.51	0.171
ΔTIR	0.32	0.550
ΔTAR	0.89	0.099
ΔTDD	−0.31	0.145
Age	0.06	0.818
Sex (Female)	0.22	0.374
Type (T2DM)	−0.40	0.138
Cigarette (+/−)	0.58	0.039
Alcohol (+/−)	1.07	0.004
Exercise (+/−)	−0.78	0.032
PMP (+/−)	−0.09	0.685

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The following abbreviations are used in this table: CSII continuous subcutaneous insulin infusion, SAP Sensor Augmented Pump, TIR Time In Range, TAR Time Above Range, TBR Time Below Range, MAGE Mean Amplitude of Glycemic Excursions, CV coefficient of variation, BMI Body Mass Index.

The following abbreviations are used in this table: A1c HbA1c, TIR Time In Range, TAR Time Above Range, TBR Time Below Range, BW Body Weight.

The following abbreviations are used in this table: MNT medical nutrition therapy, TIR Time In Range, TAR Time Above Range, TBR Time Below Range, BMI Body Mass Index.

4. Discussion

This study demonstrates significant improvements in glycemic management among PHR users, particularly in Time in Range (TIR), HbA1c levels, and Time Above Range (TAR). The primary challenge for PHR users was not hypoglycemia but rather hyperglycemia, which led participants to increase their total daily dose (TDD) of insulin to reduce TAR.

These findings underscore the beneficial role of PHRs in enhancing self-management and GC for individuals with diabetes. The observed increase in the use of smart insulin devices, likely facilitated by smartphone integration, complements these outcomes. The study suggests that PHR use supports improved insulin management and lifestyle adjustments, such as dietary changes and increased physical activity. Notably, in cases where TIR improved, some participants reduced their TDD, reflecting the positive impact of lifestyle modifications. While the results are promising, the study has limitations, including its retrospective design and potential selection bias due to voluntary PHR use, which may affect the generalizability of the findings.

Our findings align with prior research, such as a study that reviewed the role of Personal Health Records (PHRs) in diabetes self-management, showing improvements in GC and self-care behaviors. Although this study noted enhanced HbA1c reduction and increased TIR, further research is needed to examine the long-term effects of PHRs on psychosocial outcomes, such as diabetes-related distress [10]. Further supporting these findings, Kim et al. demonstrated in a randomized controlled trial that PHR use significantly improved GC and enhanced patient activation in diabetes management [11], highlighting the role of PHRs in promoting engagement and adherence to self-management practices. Supporting our findings, Seo et al. demonstrated in a retrospective observational study that the use of mobile PHRs significantly contributed to HbA1c regulation among diabetes patients [12]. This study highlights the practical benefits of mobile PHRs in enhancing long-term blood glucose control, reinforcing the value of integrating mobile technologies into diabetes management.

In a recent systematic review, Brands et al. examined the broader impact of patient-centered digital health records on health outcomes, emphasizing improved self-management and patient engagement across various chronic conditions, including diabetes [13]. Their findings further validate the potential of PHRs as valuable tools for enhancing health outcomes in diabetes management by fostering patient-centered care and active participation in self-care activities. Additionally, Morris et al. conducted a systematic review analyzing the impact of digital health interventions on health and social care utilization and associated costs in type 2 diabetes management [14]. Their findings underscore the potential for PHRs and related technologies to not only improve health outcomes but also reduce healthcare expenditures by supporting more efficient resource utilization.

With the advent of new digital and wearable technologies, it is now feasible to quantify not only overall health outcomes but also the influence of individual factors, such as person behaviors, on these outcomes. Traditional, infrequent measurements like HbA1c may be insufficient for persons who perform numerous self-management tasks daily without clear indicators of their effectiveness or impact. In the absence of such feedback, the frequency and perceived burden of these tasks can significantly influence clinical outcomes [15]. Our study posits that PHR can offer significant opportunities for persons to discern the secific impact of distinct behavioral changes on clinical outcomes. By incorporating PHR, persons may establish a habit of recording not only blood glucose levels and TDD but also dietary and exercise details, leading to heightened dietary awareness. Sharing this information with healthcare institutions might create a sense of supervision by medical staff, potentially enhancing motivation. Additionally, dietary and exercise habits might be effectively modified through advice from medical staff. Interventions via PHR could also alleviate the sense of isolation often associated with managing lifestyle diseases. For instance, a study in Japan targeting hypertensive persons reported the effectiveness of PHR in inducing behavioral changes [16]. Our study suggests a similar potential in the context of diabetes management.

Like Heal2sync®, PHR systems are widely adopted in Japan. DialBetics', designed for self-management of lifestyle habits and home monitoring of metrics such as blood glucose and blood pressure, demonstrated significant improvements in its user group. After three months of intervention, the DialBetics group showed a notable reduction in HbA1c levels (from 7.10 $\pm$ 1.00% to 6.7 $\pm$ 0.70%, $p = 0.015$) compared to the control group (from 7.00 $\pm$ 0.90% to 7.10 $\pm$ 1.10%, p = not significant [NS]). Similarly, fasting blood glucose levels improved significantly (from 140.2 $\pm$ 33.5 mg/dL to 134.7 $\pm$ 24.6 mg/dL, $p = 0.019$) compared to the control (from 127.4 $\pm$ 26.9 mg/dL to 144.3 $\pm$ 46.5 mg/dL, p = NS) [17,18]. In the United States, BlueStar (Welldoc), an FDA-approved medical device, reported a 0.8% decrease in Glucose Management Indicator (GMI). Reductions in TAR (-18.4%, $p < 0.050$) and an increase in TIR (15%, $p = 0.016$) were also observed. Notably, in individuals who logged events such as medications, exercise, food, weight, sleep, and blood pressure, a significantly higher total rate of event logging was found in those with a baseline mean glucose $\leq$180 mg/dL ($p = 0.006$), with higher rates of logging in medication

($p < 0.001$), exercise ($p < 0.001$), food ($p = 0.007$), and sleep ($p < 0.001$). These benefits are attributed not only to the recording of health information through device integration but also to appropriate lifestyle and treatment advice [19].

The utilization of the Patient Management Platform at Kameoka Municipal Hospital, our affiliate, is notably low (n = 3, 37.5%). This may be attributed to the perception that monitoring one's lifestyle, particularly dietary habits, through the platform is cumbersome, which might be one of the barriers of installing PHR. Nevertheless, improvements in blood glucose management indicators were observed even without the connection to the Patient Management Platform, suggesting that PHR may independently aid in effective self-management. We checked the smartphone of all participant to see if they continue using PHR. Those who hesitate to show their phone to outperson staff might not have installed PHR.

During the follow-up period, there was minimal weight loss in both groups, which is evident not only from the absence of increase in HDL-C (HDL cholesterol) but also from the lack of decreases in LDL-C (LDL cholesterol) and TG (Triglyceride). (refer to Table A1) A reduction of approximately 5% in body weight is necessary for the improvement of parameters such as decrease in HbA1c, LDL-C and TG, and increase in HDL-C [20]. Early implementation of nutritional therapy and increasing its frequency have been shown to effectively improve hyperglycemia. Dietary therapy by registered dietitians has been reported to show significant improvements in weight loss, HbA1c, and LDL-C reduction compared to interventions by other healthcare staff [21]. In the PHR group, reception of medical nutritional treatment, smoking cessation, non or occasional drinking, and habit of taking exercise were significantly associated with ΔBW%. Improve in self-management of lifestyles including diet enabled users to gain weight loss, therefore, nutritional therapy can be contributing factors. Although the percentage of those who underwent nutritional therapy was significantly higher in PHR group (Table A1), the number of people who received nutritional therapy was relatively less (n = 8, 32.0%). The reason of low percentage of individuals who received nutritional therapy may be similar to low usage of the Patient Management Platform. While this study demonstrates promising outcomes, it has limitations. Additionally, studies on hyperinsulinemic children emphasize the need for pediatric-specific cardiovascular risk indices. Commonly used adult markers, such as the lipid accumulation product index, may not apply accurately to younger populations. However, indices like HOMA-IR and IGF-1 levels have shown greater diagnostic accuracy for hyperinsulinemia in children [22].

In this study, we unfortunately did not collect indicators of coronary artery risks in this cohort, such as waist circumference and HOMA-IR. The retrospective design and potential selection bias from voluntary PHR use may affect the generalizability of the results. The study's sample size is relatively small, and more extensive age groups should be considered in future research to accumulate more cases. The age of PHR users was lower (52.2 ± 18.3 vs. 65 ± 1.0, $p = 0.0005$), which could affect the study results. Although PHR usage appears feasible even for older people with family support, the study did not collect data on motivation or satisfaction with treatment, which could affect outcomes. It is also possible that initially highly motivated individuals were more likely to agree to use PHR, and these participants may generally possess higher health literacy influenced by factors like education and occupation, which were not assessed. Lastly, the follow-up period was relatively short, and while the continuation rate of PHR usage was 100%, its long-term utility and long-term vascular complications requires further investigation.

5. Conclusions

The study demonstrates that PHR systems hold potential in enhancing diabetes management, improving GC, and facilitating self-management practices. These findings lay the groundwork for future research, which should aim to overcome the current study's limitations. Important areas for future exploration include the long-term impact of PHR systems on diabetes management, their effectiveness in diverse person populations, and

broader healthcare settings. This comprehensive approach will provide more conclusive insights into the efficacy and applicability of PHR systems in diabetes care.

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Institutional Review Board Statement: This cohort study received approval from the Research Ethics Committee of Kyoto Prefectural University of Medicine (Approval No. ERB-C-1876, approval date 10 November 2020) and adheres to the principles of the Declaration of Helsinki.

Informed Consent Statement: Patient consent was waived as this study was approved by the ethics committee as a study not requiring individual informed consent. The KAMOGAWA cohort study included diabetic patients from several outpatient clinics, including Kyoto Prefectural University of Medicine (KPUM, Kyoto, Japan) and Kameoka Municipal Hospital (Kameoka, Japan), and received approval from the Research Ethics Committee of Kyoto Prefectural University of Medicine (approval number: ERB-C-1876, 10 November 2020), and conducted an opt-out procedure as a cohort study that complied with the principles of the Declaration of Helsinki and did not require informed consent. In this study, outpatients at Kyoto Prefectural University of Medicine (KPUM, Kyoto, Japan) and Kameoka Municipal Hospital (Kameoka, Japan) were included in the study.

Data Availability Statement: The data that support the findings of this study are available from the corresponding author, [Hamaguchi M], upon reasonable request.

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Dainippon Pharma Co., Ltd., Novo Nordisk Pharma Ltd., Kowa Pharma Co., Ltd., Ono Pharma Co., Ltd., Eli Lilly Japan K.K., Sanwa Kagaku Kenkyusho Co., Ltd., Taisho Pharma Co., Ltd., AstraZeneca K.K., Bayer Yakuhin, Ltd., Abbott Japan Co., Ltd., Mochida Pharma Co., Ltd., Medtronic Japan Co., Ltd., Teijin Pharma Ltd., Arkray Inc., Nipro Corp., and TERUMO C. The other authors declare that they have no competing interests.

Abbreviations

The following abbreviations are used in this manuscript:

PHR	Personal Health Record
A1c	HbA1c
TIR	Time In Range
TAR	Time Above Range
TBR	Time Below Range
BMI	Body Mass Index
CGM	Continuous Glucose Monitor

Appendix A

Appendix A.1

The Health2sync® app can be used on smartphones (Figure A1). This app analyzes user-recorded data such as blood glucose levels, blood pressure, weight, medication status, diet, and exercise, creating opportunities for users to reflect on their behaviors and thereby supporting self-health management.

It allows for the display of CGM data when connected to FreeStyle® LibreLink. And it also enables data extraction through connectivity with certain home blood pressure monitors, blood glucose meters, and weight scales equipped with communication capabilities.

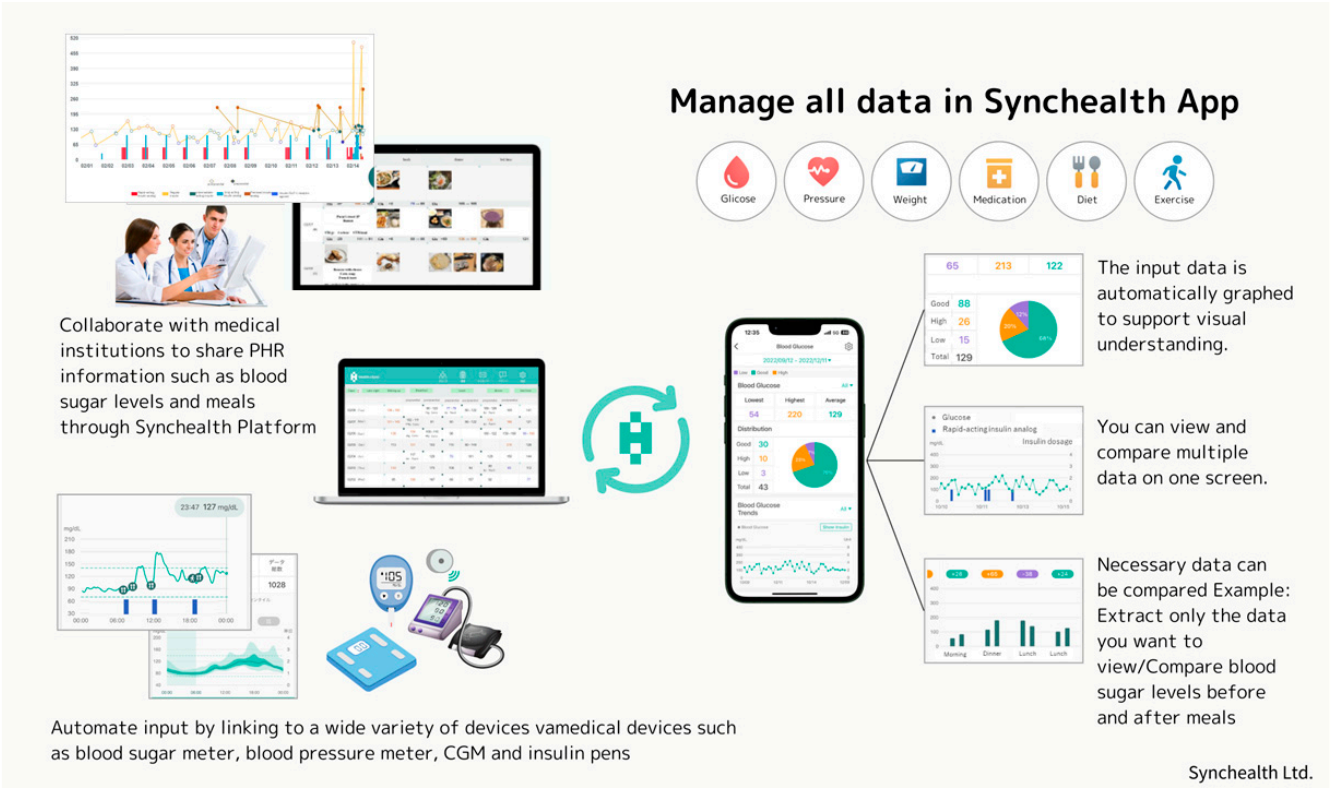

Figure A1. This is a figure. It shows usage of Health2Sync® app and how users collaborate with medical institutions to share PHR information.

Appendix A.2

Table A1 displays the baseline characteristics of all participants in the current study. The median HbA1c was 7.86 ± 1.30%, and the median TIR was 60.9 ± 21.9. Number of hypoglycemia (blood glucose level < 54 mg/dL) per 2 weeks was 5.12 ± 8.15, showing less frequency in PHR group (4.08 ± 8.40). No significant differences were observed between the two groups in terms of smoking history and alcohol consumption history. However, a significant difference in exercise habits was noted in the PHR users.

Table A1. Baseline characteristics of all participants.

	Total	**PHR (+)**	**PHR (-)**	***p* Value**
	N = 212	**N = 25**	**N = 187**	
Age (years)	63.6 ± 14.9	52.2 ± 18.3	65 ± 1.0	0.0005
Age (<18 years)	0	0	0	
Age (18–65 years)	108 (50.9)	15 (0.6)	93 (49.8)	
Age (>65 years)	104 (49.1)	10 (0.4)	94 (50.2)	
Sex (Female)	88 (41.5)	7 (28.0)	81 (43.3)	0.136
BMI (kg/m^2)	23.6 ± 6.1	25.8 ± 7.2	23.4 ± 0.4	0.159
Type (T2DM)	136 (64.2)	15 (60.0)	121 (64.7)	0.056
DM medication (Insulin)				0.391
Basal supported oral therapy	36 (17.0)	6 (24.0)	30 (16.0)	
Basal-bolus treatment	164 (77.4)	19 (76.0)	145 (77.5)	
CSII/SAP	7 (3.3)	0	7 (3.7)	
Insulin dose	28.05 ± 17.8	29.1 ± 4.4	27.9 ± 1.3	0.997
Number of smart insulin user	26	12	14	<0.0001
Glucose ave	170.42 ± 45.7	187.92 ± 62.1	168.15 ± 42.7	0.317
HbA1c (%)	7.86 ± 1.3	8.2 ± 1.8	7.8 ± 1.2	0.65
TIR (%)	60.87 ± 21.9	53 ± 30.2	61.7 ± 1.5	0.41
TAR (%)	37.2 ± 23.6	45.4 ± 31.4	36.1 ± 22.2	0.339
TBR (%)	3.36 ± 5.9	1.55 ± 3.3	3.62 ± 6.2	0.017
MAGEave	121.14 ± 38.3	116.32 ± 31.9	121.76 ± 39.1	0.532
CV	33.14 ± 8.0	29.3 ± 6.3	33.6 ± 0.6	0.004
Number of Hypoglycemia per 2 weeks	5.12 ± 8.15	4.08 ± 8.40	5.40 ± 8.13	0.07
Cigarrete				0.374
Never smoker	129 (60.8)	15 (60.0)	114 (61.0)	
Ex-smoker	59 (27.8)	8 (32.0)	51 (27.3)	
Current smoker	37 (17.5)	1 (4.0)	36 (19.3)	
Alcohol	98 (46.2)	7 (28.0)	91 (48.7)	0.345
Exercise				0.003
regulary	71 (33.5)	3 (12.0)	68 (36.4)	
rare	102 (48.1)	22 (88.0)	81 (43.3)	
Receiving Medical Nutritional therapy	27 (12.7)	8 (32.0)	19 (10.2)	0.048

This table indicates baseline characteristics of all patients. We enrolled 212 persons, of whom 124 (58.5%) were male, and 136 had been diagnosed with type 2 diabetes. The median age of the study participants was 63.6 ± 14.9 years, and the median Body Mass Index (BMI) was 23.6 ± 6.10 kg/m^2. Of the participants, 17% were undergoing basal supported oral therapy, while 77.4% were receiving basal-bolus treatment. Smart insulin devices, such as NovoPen® and NovoPen Echo Plus®, which can be integrated with a smartphone through an app, were more commonly chosen by PHR users. A significant trend towards the use of smart insulin devices was observed, likely due to their smartphone connectivity capabilities.

Appendix A.3

In PHR group, the TIR significantly extended (ΔTIR 17.3 ± 27.2 vs. −1.10 ± 17.8, p = 0.002), and HbA1c decreased (ΔA1c −0.89 ± 1.34 vs. −0.22 ± 1.02, p = 0.004). A significant reduction was also observed in the Time Above Range (TAR) in the PHR group (ΔTAR −17.8 ± 27.4 vs. −1.80 ± 18.2). An increase in total daily dose (TDD) was noted in the PHR group (4.40 ± 4.36 vs. 0.50 ± 0.51, p = 0.017). Change in BW was not significant in PHR group (ΔBW −0.19 vs. −0.27, p = 0.957). Moreover, the number of hypoglycemia per 2 weeks did not show significant decrease in PHR group (−0.16 vs. 0.65, p = 0.453).

Table A2. Changes in glycemic outcomes in all participants.

	Total	PHR (+)	PHR (−)	*p* Value
	N = 212	N = 25	N = 187	
ΔA1c	−0.30 ± 0.911	−0.89 ± 1.34	−0.22 ± 1.02	0.004
ΔTIR	0.95 ± 23.4	17.3 ± 27.2	−1.11 ± 17.8	0.002
ΔTAR	−0.42 ± 20.8	−17.8 ± 27.4	1.76 ± 18.7	0.001
ΔTBR	−0.53 ± 4.87	0.44 ± 1.61	−0.65 ± 5.14	0.064
ΔTDD	0.97 ± 5.79	4.36 ± 9.81	0.50 ± 5.40	0.957
ΔBW	−0.26 ± 1.86	−0.19 ± 4.43	−0.27 ± 1.80	0.957
Change in the number of hypoglycemia	0.55 ± 3.62	−0.16 ± 3.21	0.65 ± 4.23	0.453

This table displays the changes in glycemic outcomes in all participants. TIR of PHR users significantly extended (ΔTIR 17.3 ± 27.2 vs. −1.10 ± 17.8, $p = 0.002$), and HbA1c decreased (ΔA1c −0.89 ± 1.34 vs. −0.22 ± 1.02, $p = 0.004$). A significant reduction was also seen in the TAR (ΔTAR −17.8 ± 27.4 vs. −1.80 ± 18.2). Increase in TDD was noted in the PHR group (4.40 ± 4.36 vs. 0.50 ± 0.51, $p = 0.017$). There was no significant change in BW between both groups (ΔBW −0.19 vs. −0.27, $p = 0.957$). The number of hypoglycemia per 2 weeks did not show significant decrease in PHR group (−0.16 vs. 0.65, $p = 0.453$).

Appendix A.4

During the follow-up period, there was minimal weight loss in both groups, which is evident not only from the absence of increase in HDL-C (HDL cholesterol) but also from the lack of decreases in LDL-C (LDL cholesterol) and TG (Triglyceride).

Table A3. Changes in biochemical data.

	V1		*p*	V2		*p*
	PHR (+)	PHR (−)		PHR (+)	PHR (−)	
AST (IU/L)	23.8 ± 15.1	23.3 ± 9.00	0.440	23.1 ± 12.2	24.5 ± 13.1	0.231
ALT (IU/L)	24.6 ± 19.0	22.3 ± 15.9	0.870	25.7 ± 25.8	21.4 ± 12.6	0.942
T-C (mg/dL)	201.2 ± 11.5	199.0 ± 4.20	0.990	198.8 ± 41.3	203.3 ± 55.1	0.863
HDL-C (mg/dL)	68.7 ± 22.0	64.6 ± 20.8	0.431	65.3 ± 21.3	71.4 ± 23.7	0.209
LDL-C (mg/dL)	113.5 ± 49.1	109.6 ± 36.8	0.762	118.4 ± 42.8	113.0 ± 42.9	0.442
TG (mg/dL)	177.1 ± 136.7	138.4 ± 107.0	0.221	172.9 ± 95.6	137.4 ± 100.8	0.053
Cr (mg/dL)	0.97 ± 0.80	1.04 ± 0.87	0.042	1.25 ± 1.75	1.04 ± 0.93	0.192

This table indicates changes in biochemical data of both groups. There was absence of increase in HDL-C (HDL cholesterol), and the lack of decreases in LDL-C (LDL cholesterol) and TG (Triglyceride). (V1 = the time they were suggested to use PHR, V2 = the end of 6 months follow up period).

Appendix B

This table shows changes in biochemical data, body weight, BMI, and CGM metrics of the Individuals who had BMI of over 25 kg/m^2 before intervention.

Table A4. Characteristics, changes in biochemical data, body weight, BMI, and CGM metrics of the Individuals who had BMI of over 25 kg/m^2 before intervention SIP = Smart Insulin Pen, MNT = Medical Nuturitional Treatment, PMP = Patient Management Platform, 1 = Yes, 0 = No, (-) = no data, Others (Type) = Pancreatic diabetes.

Patient ID	BMI-1	BMI-2	ΔA1c	ΔTIR	ΔTAR	ΔTBR	ΔBW	ΔBW (%)	ΔTDD	OHA Arrengement	Sex	Age	Type	SIP	MNT	PMP	Cigarette	Alcohol	Exercise	AST-1 (IU/L)	ALT-1 (IU/L)	Tcho-1 (mg/dL)	TG-1 (mg/dL)	Cre-1 (mg/dL)	HDLC-1 (mg/dL)	LDLC-1 (mg/dL)	AST-2 (IU/L)	ALT-2 (IU/L)	Tcho-2 (mg/dL)	TG-2 (mg/dL)	Cre-2 (mg/dL)	HDLC-2 (mg/dL)	LDLC-2 (mg/dL)
No.1	36.3	35	-0.6	31	-31	0	-3.5	-3.5	19	Change from Luseogliflozin 5 mg to Dapagliflozin 10 mg	M	28	T2	1	1	1	0	1	0	36	77	228	455	0.52	45	0	39	45	204	201	0.78	64	100
No.2	28.4	28.7	-0.2	15	-18	3	1	1.23	12		M	53	T1	0	1	0	1	1	0	16	17	157	318	1.52	35	58	16	15	167	274	1.66	37	75
No.3	25	25.7	1.1	13	-14	1	2	2.85	2		M	69	T2	1	0	0	0	1	0	6	9	114	133	2.52	37	50	6	8	119	108	2.97	40	57
No.4	48.2	49.4	-1	12	-12	0	0	0	8	Add Imeglimin 1000 mg	M	31	Others	0	0	1	0	0	1	24	31	202	243	0.48	70	83	20	27	160	379	0.48	59	25
No.5	25.5	23	-3	73	-73	0	-5.9	-8.43	-8	Withdraw Metformin, Pioglitazone, GLUBES Combination Tablets	M	57	T2	0	1	0	0	0	0	19	22	192	116	1.35	53	122	24	34	178	134	1.6	44	110
No.6	31.7	33.9	-4.1	55	-56	1	6.1	6.78	-8		M	68	T2	0	1	0	1	1	0	80	77	224	202	0.74	67	195	34	33	183	251	0.8	75	81
No.7	30.1	30.1	-0.6	13	-13	0	0	0	13	Add dapagliflozin	F	52	T1	1	0	0	0	1	0	26	29	254	131	0.85	50	185	22	24	248	173	0.84	46	176
No.8	37.7	36.1	-1.6	50	-54	4	-4.6	-4.42	10		F	54	T2	1	1	1	0	1	0	14	16	329	575	3.9	65	173	13	15	233	265	8.88	61	123
No.9	26.9	26.9	-1.2	-1	1	0	0	0	7		F	74	T2	1	0	0	0	0	0	19	13	189	173	0.85	66	88	20	14	176	88	0.9	59	113
No.10	27	27	0	-7	5	2	0	0	0		M	25	T1	0	0	0	0	1	0	-	-	257	110	-	92	143	13	12	241	253	0.93	59	132
No.11	30.4	30.3	-1.2	12	-12	0	-0.2	-0.26	17		M	68	T2	0	0	0	1	1	1	28	30	161	167	0.58	36	92	19	21	244	209	0.54	47	156

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