



Effect of Adding Computerized Insulin Dose Adjustment Algorithms (CIDAA) to a Remote Patient Monitoring (RPM) Program on A1C Levels

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Objective

To evaluate the effect of FDA-cleared CIDAA (Insulin Insights™) incorporated into an RPM program on A1C levels.

Methods

The population studied was enrolled in a Managed Medicare Advantage plan in primary, multi-specialty physician groups with some medical groups having an RPM program and others not. In RPM programs, patients measure glucose remotely which are sent to their HIPAA approved portal. Values <70 mg/dL and >200 mg/dL alert a health educator who contacts the patient and counsels them on avoiding subsequent episodes. Type 2 diabetic patients receiving insulin for greater than 6 months with A1C levels >8.0% were approached regarding their interest in participating in a research study. Those agreeing were divided into three cohorts. Group A was from the RPM program to which Insulin Insights™ was incorporated. Group B was also enrolled in the RPM program but Insulin Insights™ was not available to their providers. Group C was not enrolled in the RPM program and was designated as Usual Care.

Patients in Groups A and B were loaned a Bionime™ Bluetooth glucose meter whose glucose readings were sent to the RPM program. Each glucose reading from Group A patients was then sent on to Mellitus Health. Reports were sent to Group A providers with recommendations for possible insulin dose adjustments that could be accepted or modified every 2 weeks if at least one insulin dose needed to be changed or every 3 weeks if none did. Patients in Group C continued to use their own off-study glucometers. Patients in Groups A and B were not supposed to receive additional non-insulin drugs throughout the study.

The primary outcome was the change in A1C levels from baseline to 6 months. A secondary outcome in Groups A and B were the number of high (>200 mg/dL) and low (<70 mg/dL) alert values during the study. Baseline HbA1c levels were analyzed by a non-parametric one-way ANOVA. Changes in HbA1c levels were analyzed by Dunn's test for multiple differences. Alert values were analyzed by an asymptomatic test of homogeneity for the Poisson rates from 2 groups. The number of patients receiving a new non-insulin drug was analyzed by Chi square tests. Significance was accepted at P < 0.05 (2-tailed).

Results

The demographic characteristics are shown in the top of Table 1 and the clinical outcomes towards the bottom of Table 1 and the Figure. There were no significant differences among the baseline A1C levels of the 3 groups. A1C levels fell twice as much in Group A compared to Groups B and C. The decreases in Groups B and C were the same. Total alerts and values >200 mg/dL were significantly less in Group A vs B while values <70 mg/dL were not significantly different. There were no visits to the emergency room for hypoglycemic episodes in Groups A and B while 6 patients in Group C did make such a visit. In Group A, the initial daily amount of insulin taken per patient was 74 units that rose to 108 units by the end of the study, a 46% increase. The providers increased the patients' insulin units by 50% of the total amount recommended by Insulin Insights™.

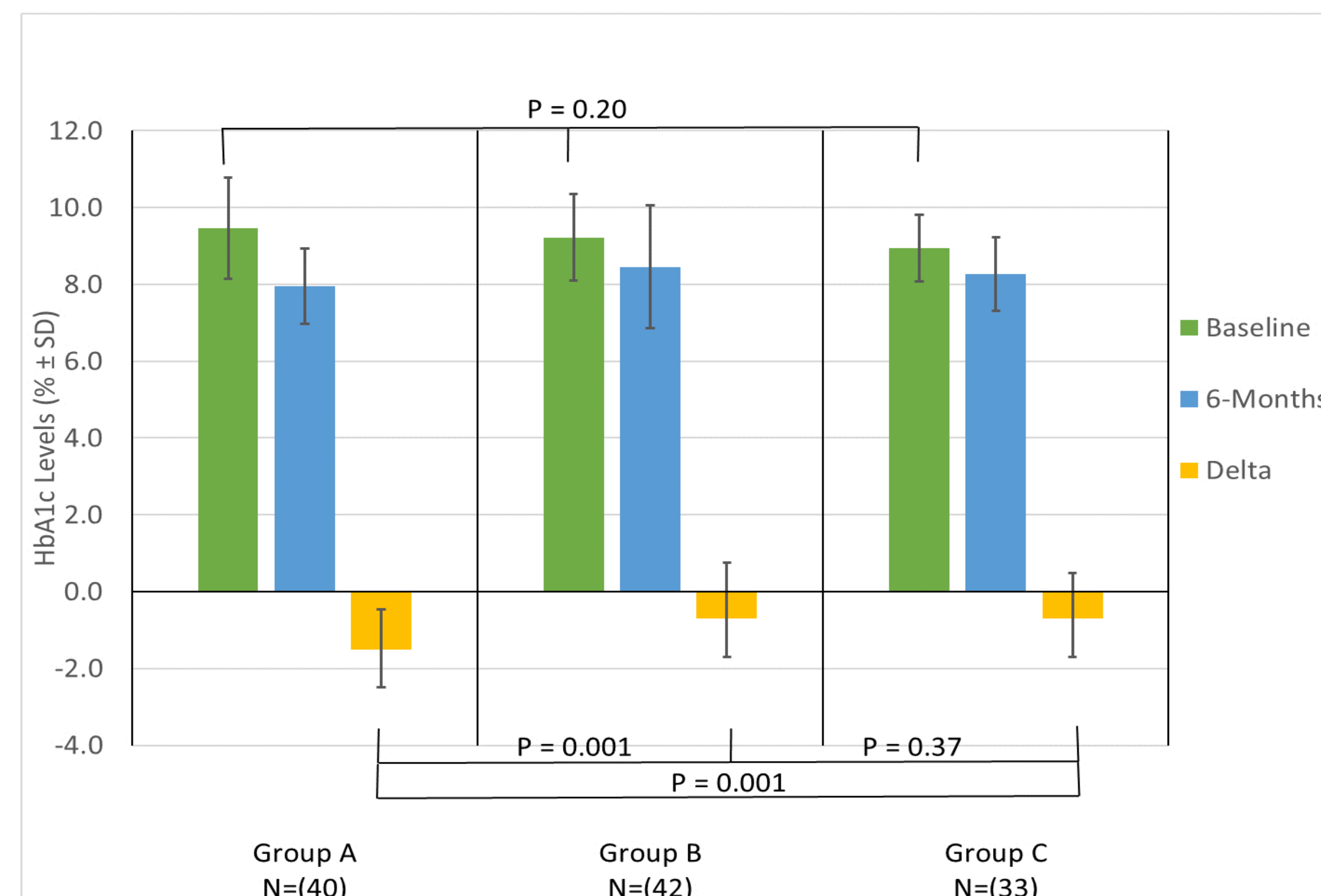
Anti-hyperglycemic medications are shown in Table 2. The initial and final insulin regimens were similar among the 3 groups. However, the number of patients receiving new non-insulin drugs added to their insulin regimens was increased in Groups B and C compared to Group A with the difference between Groups A and B showing a trend, between Groups A and C being significantly different and not significantly different between Groups B and C.

Results

Table 1– Demographics and Clinic Outcomes

	Group A (N = 40)	Group B (N = 42)	Group C (N = 33)
Age (Years ± SD)	69.1 ± 8.1	67.1 ± 6.9	69.3 ± 9.7
Sex (females/males)	19/21	21/20	18/14
BMI (kg/m ² ± SD)	35.4 ± 6.9	34.9 ± 7.2	36.4 ± 9.2
Baseline A1C (% ± SD)*	9.5 ± 1.3	9.2 ± 1.1	9.0 ± 0.9
Six Month A1C (% ± SD)	8.0 ± 1.0	8.5 ± 1.6	8.3 ± 0.9
A1C Change (% ± SD)†	-1.5 ± 1.0	-0.7 ± 1.5	-0.7 ± 1.2
All alerts (N)‡	1177	1320	-
Alerts >200 mg/dl (N)§	942	1111	-
Alerts <70 mg/dl (N)	235	209	-

*Groups A, B and C, P = 0.20; †Group A vs B, P = 0.02; ‡Group A vs B, P = 0.002; ||Group A vs B, P = 0.14; ‡Group A vs B, P = 0.001; Group A vs C, P = 0.001; Group B vs C, P=0.37



Results

Table 2 – Anti-Hyperglycemic Medications

Insulin Regimen	Group A (N = 40)		Group B (N = 42)		Group C (N = 33)	
	Initial	Final	Initial	Final	Initial	Final
Basal alone (N)	18	21	17	18	16	17
Basal/Bolus (N)	17	12	17	18	12	11
Self-Mixed Split (N)	5	5	4	2	4	4
Premixed (N)	-	-	2	2	1	1
U-500 Regular (N)	-	2	1	1	-	-
Lispro only (N)	-	-	1	1	-	-
Non-insulin anti-diabetes drugs added (N)*	-	4	-	10	-	13

N – number of patients; *Group A vs B, P = 0.087; Group A vs C, P = 0.003; Group B vs C, P = 0.17

Discussion

Insulin Insights™ more than doubled the decrease in A1C levels in patients enrolled in an RPM program compared to both those also enrolled in the RPM program but whose providers did not have access to CIDAA and those followed in usual care. This improvement occurred in the absence of increased hypoglycemia and with a 46% increase in insulin doses by the end of the study. The providers increased the patient's insulin units by 50% of the amount recommended by Insulin Insights™, likely due to the providers' concerns about potential hypoglycemia. However, higher adherence to the recommended insulin unit increases would have resulted in greater improvement. The modest improvements in the 2 control groups may have been at least partially due to significantly more patients receiving new non-insulin anti-diabetes drugs as well as the Hawthorne effect as both patients and their providers were aware of enrollment into the study. Because both Groups B and C had similar reductions in A1c while both benefited from the Hawthorne effect and an increase in non-insulin anti-diabetes drugs, it appears that Group B's RPM program, which provided lifestyle counseling around high glucose readings, was not effective in improving diabetes control.

Conclusions

- Although the low alert values of RPM prevented emergency room visits for hypoglycemia, providing only lifestyle counselling for high alert values did not improve diabetes control compared to usual care.
- Poorly controlled, insulin-requiring patients are greatly under-insulinized and require larger and appropriate increases in insulin doses.
- CIDAA provided by Insulin Insights™ can effectively and safely improve diabetes control in patients receiving insulin who are undergoing RPM.