electronic caregiver

ABSTRACT

Diabetes control has been linked to both better health and decreased morbidity and mortality. Typically, levels of diabetes control have been inferred from frequent blood glucose level assessment and measurement of glycated hemoglobin levels (A1c). In targeted efforts to support better day-to-day control over diabetes, remote patient monitoring (RPM) technology is now being dispatched into the home setting. This technology provides a variety of support mechanisms for facilitating better disease management. Unfortunately, little is known regarding the influence and/or efficacy of available RPM technology. As such, an in-depth assessment of the effectiveness of available technology is needed. Thus, the purpose of this investigation is to attempt to quantify the influence of RPM technology on diabetes management.

A retrospective chart review was conducted across a sample of 77 patients diagnosed with Type II diabetes who were prescribed remote patient monitoring technology. Variables extracted from the retrospective chart review included RPM status and historic A1c levels. Test-retest analyses were utilized to determine changes in measured A1c levels prior to and following the implementation of RPM technology into their care plans.

Analysis of A1c data revealed remote patient monitoring may enhance day-to-day control and management of diabetes. It was observed that measured A1c levels increased significantly *($p < 0.01$)* prior to RPM implementation with an increase observed across 81% of the sample. Following implementation of RPM, A1c levels were observed to decrease significantly *($p < 0.01$)* with a decrease observed across 82% of the sample.

These findings suggest that the incorporation of RPM into a patient's plan of care may facilitate better day-to-day control of blood glucose levels and Type II diabetes. Enhanced day-to-day control of the disease process in Type II diabetes has been repeatedly linked with decreases in both mortality and morbidity. The observed decrease in A1c measurements following RPM implementation suggests that this technology can effectively support individuals with a Type II diabetes diagnosis. However, although the findings of this initial work are exciting, additional investigations with increased design rigor are needed to confirm these initial findings.

Remote Patient Monitoring Technology May Enhance Disease Control in Type II Diabetes

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1. INTRODUCTION

The inclusion of remote patient monitoring (RPM) technology in the chronic disease management setting is not new. However, with the recent implementation of reimbursement for RPM, medical professionals have begun incorporating these technologies into care plans more frequently. Unfortunately, little research describing the influence and efficacy of RPM is currently available. As such, it is vital that the RPM community work to develop valid evidence of the effectiveness of these technologies.

As such, this report functions to serve three primary purposes:

1) To provide a better understanding of remote patient monitoring on levels of variability of glycated hemoglobin, known as an HbA1c (A1c) value.

2) To describe the influence of remote patient monitoring technology on a sample of Type II diabetes patients.

3) To provide a better understanding of the influence of duration of remote patient monitoring on A1c levels.

In doing so, this white paper provides an initial high-level overview of the influence of RPM technology. While continued research is necessary, and currently being carried out, the findings of this work describe the effects RPM technology has on chronic disease management, specifically in terms of Type II diabetes.

2. AIMS

The aims of this document are:

1) To outline the need for the designed Electronic Caregiver® remote patient monitoring (RPM) system;

2) To describe the process associated with RPM implementation and conduction;

3) To initially describe the influence of RPM on patients diagnosed with Type II diabetes;

4) To quantify observed changes in glycated hemoglobin (A1c) levels across patients utilizing RPM to assist in disease management;

and

5) To pose subsequent inquiries based specifically on the results of analyses conducted herein.

3. BACKGROUND

3.1 General Information

With the rapid increase in the population of older adults, the epidemiology of chronic disease has dramatically shifted toward the elderly.[1] Diabetes, which also follows this trend, is typically considered a risk factor for disability and/or functional decline.[2] This functional decline can be manifested physically and physiologically with functional impairment typically occurring across a variety of bodily systems. As a result, effective diabetes management is typically thought to include:

- A multidisciplinary team of providers[3];
- Consistent reinforcement of patient education[4];
- Proactive care delivery consisting of:
  - Self-management support[5],
  - Decision support[5],
  - Clinical information systems[5],
  - Community resources[5],

Although there has been some success in improving care for the diabetic patient, diabetes is still increasing at an alarming rate. It is currently estimated that 9.4% of the US population (~30.3 million people) have diabetes, with 7.2 million having yet to be diagnosed.[6] Additionally, diabetes knows no racial, gender or ethnic boundaries with 1.5 million new cased diagnosed across all races, ethnicities and genders in 2015. [6] It is also estimated that there were more than 7 million hospital discharges among patients diagnosed with diabetes in 2014, with an additional 14.2 million emergency department visits reported for those diagnosed with the disease. [6] These facts, along with the 2012 estimated cost of $245 billion for diagnosed diabetes cases, demonstrate a drastic need for evidence-based enhancements to the current diabetes care paradigm. [6]

3.2 Glycated Hemoglobin (A1c)

Glycemic fluctuations occur regularly and for various reasons. These fluctuations are characterized by changes in plasma glucose and can be problematic or potentially serious. These fluctuations range across the spectrum of possible outcomes, from minor annoyances to debilitating and deadly. Thus, effective control of blood glucose is a vital component of clinical care efforts designed to support disease management across diabetic patients.[7]

The prevalence and consequences of diabetes has led to the identification of numerous features associated with daily blood glucose management. One specific feature of interest in diabetes management is the level of glycated hemoglobin(A1c). The level of A1c has been deemed a valid measure describing the average blood glucose levels over a three-month span.[8] It is also recognized as a valid assessment of long-term glycemic control in patients diagnosed with Type II diabetes as well as being the focus of therapeutic interventions with the goal of achieving a target A1c value.[9-10] This interventive focus on A1c levels is vital in that enhanced glycemic control has been associated with significant reductions in poor diabetes outcomes, as well as a decrease in the probability of microvascular events, cataract extraction retinopathy deterioration, myocardial infarction risk and more.[11]

3.3 Advanced Remote Patient Monitoring

Remote patient monitoring (RPM) can be defined as the capture and transmission of real-time physiological data of a patient for instant and retrospective review.[12] Due to the emergence of new technologies RPM has evolved from elementary methods such as patient phone interviews into the utilization of a broad range of biosensors and applications that measure and report physiological data. The Electronic Caregiver Pro Health system is an RPM technology that monitors a patient by providing:

- Medication management through Electronic Caregivers medication reminder feature.
- Health vital management via the Pro Health console and peripheral devices that remind the patient to measure and monitor blood pressure, blood glucose, blood oxygen saturation, weight, heart rate, and body temperature.
- Real time vitals anomaly detection that notifies the patient and/or responsible party when a measurement is outside of the individuals provisioned threshold.
- A comprehensive record of patient vital history in-home for physician to review.
- Early intervention with a remote wrist pendant that with the push of a button gives the patient 24/7 access to EMT services in case of emergency.

Diabetes management incorporates tracking patient blood glucose and medication adherence outside of the clinical setting. This continual monitoring is to prevent the consequences that hyperglycemic and hypoglycemic states have on homeostasis. These states can be precursors to medical emergencies such as hyperosmolar hyperglycemic state and diabetic ketoacidosis which require immediate emergency response.[13-14] It is also known that lack of compliance to a medication regimen has a negative effect on glycemic control.[15] Electronic Caregivers medication and health vital management features allow for continual monitoring and prevention of these conditions, which could potentially improve patient outcomes.

4.Technical Content

4.1 The Electronic Caregiver Pro Health System

The Electronic Caregiver Pro Health system is an LTE cellular console that connects via Bluetooth to telehealth and vitals monitoring peripheral devices such as:

- Blood Pressure Monitor
- Pulse Oximeter
- Glucometer
- Weight Scale
- Thermometer
- Emergency Response Remote Pendant

The console includes a 2-way speaker, emergency button, and remote pendant that automatically connects to an emergency response monitoring center. Emergency response operators can communicate with the monitored individual, dispatch emergency services, and contact responsible parties. A responsible party can be an individual's provider, family member, caregiver, or case manager. Along with emergency response access, the Pro Health's peripheral devices have the capability to program an individual's vital thresholds into a health management dashboard application, the RemoteCare 24/7 application. The application features a history of a patient's vital readings along with an alert feature that notifies the patient and responsible parties if a measured vital is outside of its provisioned threshold. Along with vitals management, a medication adherence feature can be provisioned into the ECG Pro Health system via medication alerts. A medication being taken is verified by the patient pressing the console or remote button after the alert. Medication acknowledgement data is also transferred to the RemoteCare 24/7 application and will notify responsible parties if a medication is not taken.

4.2 Study Design

In order to monitor RPM effects on Type II diabetic patient outcomes, a licensed physician prescribed the Electronic Caregiver Pro Health system as a component of a patient diabetes control program Subjects had to have been diagnosed with Type II diabetes and had 2 A1c readings taken 6 months prior to study to be eligible for participation.

Physicians conducted a retrospective review on medical records to find those who were eligible for enrollment. 77 patients were prescribed an Electronic Caregiver Pro Health console with emergency wrist pendant, peripheral devices for vitals tracking, and medication management. Although patient data are deidentified for analysis, data sharing agreements are included in the Electronic Caregiver ordering process to ensure subjects consented to terms of study.

To evaluate efficacy of RPM inclusion in diabetes control management A1c was measured at follow-up consultation and compared to the most recent pre-RPM A1c reading. Due to variation in total days monitored per individual, the analysis was followed by a comparison of pre and post readings that was grouped based on the difference between the two time points that measurements were taken.

5.Results

5.1 Data Analysis

Ninety-five A1c measurements were taken per individual pre- and post-RPM. Statistical analysis on change in measurements and days monitored per individual was performed with SPSS software. If an individual had two readings before or after enrollment in diabetes control program the minimum difference between the time points was considered. Pre-RPM and post-RPM A1c measurements, along with the difference between the two, were labeled with HBA1C_1, HBA1C_2 and HBA1C_MAG_DIFF respectively.

Table 1. Descriptive Statistics (Valid N = 95)

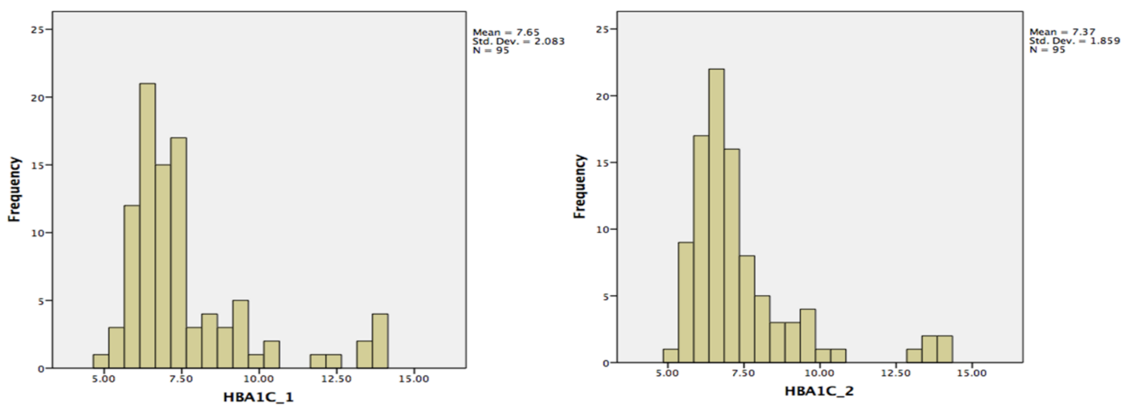
	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
HBA1C_1	9.10	4.90	14.00	7.6495	.21372	2.08311	4.339
HBA1C_2	8.90	5.10	14.00	7.3705	.19070	1.85867	3.455
HBA1C_MAG_DIF	6.40	-1.20	5.20	.2789	.07610	.74175	.550
Days Monitored	214.00	34.00	248.00	143.6000	5.66810	55.24576	3052.094

Table 2.

	Skewness		Kurtosis	
	Statistic	Std. Error	Statistic	Std. Error
HBA1C_1	1.844	.247	2.934	.490
HBA1C_2	2.119	.247	4.732	.490
HBA1C_MAG_DIF	3.727	.247	21.195	.490
Days Monitored	-.150	.247	-.893	.490
Valid N (listwise)				

A1c levels between pre and post RPM decreased from 7.6495 to 7.3705 for a difference of .2789. Variance in A1c measurements saw a decrease from 4.339 to 3.455 for an overall difference of .550. (Table 1). Skewness and kurtosis were measured to take distributional assumptions into consideration (Table 2). Pre and post treatments exhibited a normal distribution (Figure 1) HBA1C_MAG_DIF skewness statistic was measured at 3.7 which minorly violates distributional assumptions however, the independent samples t-test is robust in addressing this.

Figure 1 Hba1c Pre and Post RPM



Pre and post treatment samples distributions were split into their lower and upper percentile groups based off days monitored, and then descriptively analyzed due to the variance in time points between measurements (Table 3). The lower and upper 50th percentiles are discretely classified as .00 and 1.00. Both groups saw a decrease in mean, with the lower percentile exhibiting a difference of .0426 and the upper percentile with a decrease of .5104. (Table 3)

Table 3. Group Statistics

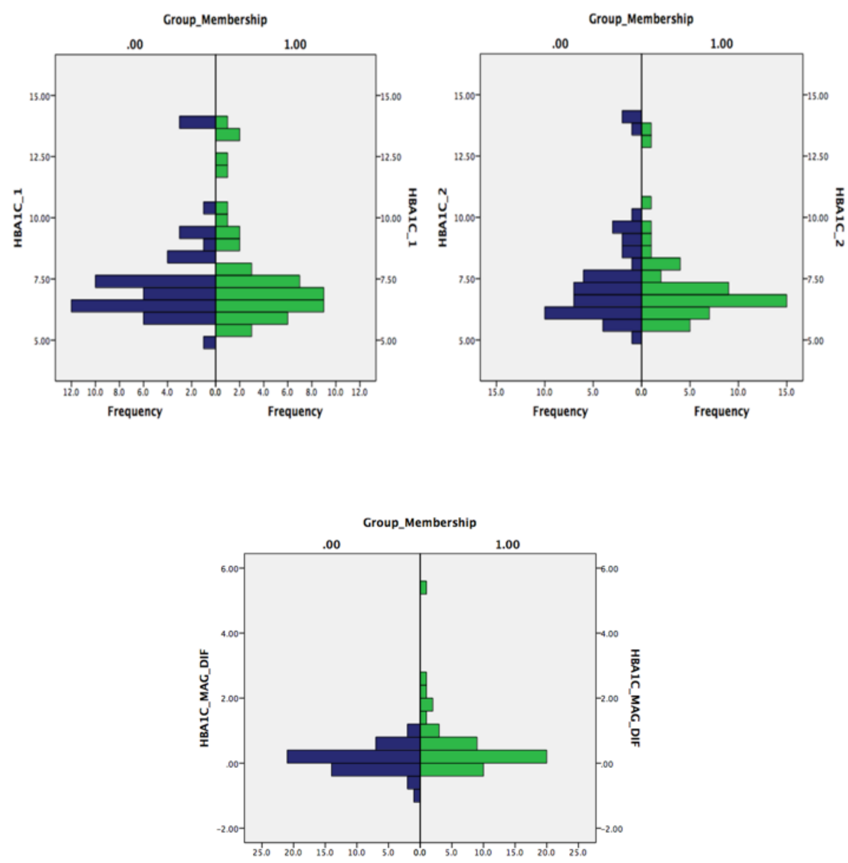
	Group Membership	*N*	Mean	Std. Deviation	Std. Error Mean
HBA1C_2	.00	47	7.5383	2.04945	.29894
	1.00	48	7.2063	1.65612	.23904
HBA1C_1	.00	47	7.5809	2.02695	.29566
	1.00	48	7.7167	2.15597	.31119
HBA1C_MAG_DIF	.00	47	.0426	.37634	.05489
	1.00	48	.5104	.92259	.13316

To address if there was any significant difference in variance and means between groups degrees of monitoring, a Levene's and a *t*-test were performed, respectively (Table 4). There was no significant difference in distributional assumptions for HbA1c_1 and HbA1c_2. However, there was a significant difference in HbA1c_MAG_DIFF groupings variance and means which could implicate inverse behavior between days monitored and glycated hemoglobin concentration. (Figure 2).

Table 4. Independent Samples Test

		Levene's Test for Equality of Variances		*t*-test for Equality of Means		
		F	Sig.	*t*	df	Sig. (2-tailed)
HBA1C_2	Equal variances assumed	1.799	.183	.869	93	.387
	Equal variances not assumed			.868	88.299	.388
HBA1C_1	Equal variances assumed	.432	.513	-.316	93	.753
	Equal variances not assumed			-.316	92.849	.752
HBA1C_MAG_DIF	Equal variances assumed	6.482	.013	-3.224	93	.002
	Equal variances not assumed			-3.248	62.487	.002

Figure 2. Group Statistics



6.Discussion

6.1 Findings

Diabetes control is centralized around management of glycemic fluctuations[16]. Glycemic control in diabetics is quantified by measuring the percentage of glycated hemoglobin, known as an HbA1c(A1c) value. In addition to A1c mean, there is also evidence that a greater A1c variability indicates an increased health risk for diabetics[17.] In this study, A1c mean and variance were both used to determine if Electronic Caregivers remote patient monitoring improved diabetic patient outcomes.

Patients who had Electronic Caregivers Pro Health system included in their prescribed plan of care showed significant decreases in A1c variance and mean values when comparing pre and post RPM intervention per individual. Furthermore, when individuals were grouped according to monitoring duration those who were monitored longer exhibited a greater change in the decrease of distribution and magnitude (Figure 2.) of A1c measurements. Although it is not indicative, these findings imply a positive relationship between diabetes control and intervention of Electronic Caregivers RPM when measured by A1c variance.

In conclusion, RPM has shown significant improvements when included in a Type II diabetes plan of care. These findings are significant however, there can still be lack of clear causal relationship between remote patient monitoring and improved diabetic patient outcomes. Therefore, it would be advisable to further investigate the aspects of RPM that contribute to these improved patient outcomes.

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