Spring 5-2018

The Effectiveness of Insulin Pump Therapy after Transition from Multiple Daily Insulin Injections In Type 1 Diabetes

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ABSTRACT

The population of patients who have been diagnosed with diabetes mellitus (Type 1 or Type 2) has been increasing in the United States. Patients with type 1 diabetes may receive insulin through delivery via insulin pump therapy (IPT) or multiple daily insulin injections (MDII). In addition to requiring insulin, other management regimens have included frequent blood glucose monitoring, checking laboratory values hemoglobin A1c (A1C), maintaining normal body mass index (BMI), keeping a balanced diet, carbohydrate counting, and exercise. The purpose of the study was to compare the retrospective data of A1C and BMI of patients with type 1 diabetes after they transition from MDII to IPT.

An investigation was conducted retrospectively using a non-experimental chart review at an outpatient endocrinology department in Northern California. Electronic data collection technology was utilized to collect information about patient's age, gender, BMI, and A1C. Data of the dependent variables, such as A1C, and BMI, were collected at baseline pre-IPT and 3, 6, and 12 months post-IPT.

Results indicated that the mean A1C decreased significantly from baseline to 3 months and 3-6 months post-IPT period. However, there was no difference in mean A1C from baseline to 12 months post-IPT. Mean BMI increased significantly from baseline to 3 months post-IPT. However, there was no difference in mean BMI from baseline to 3-6 months and baseline to 12 months post-IPT. This quality improvement research study supports that there was no significant decrease in either A1C or BMI after a patient transitions from MDII to IPT within the first 12 months.

Sima Sapkota
May, 2018

THE EFFECTIVENESS OF INSULIN PUMP THERAPY AFTER TRANSITION FROM MULTIPE DAILY INSULIN INJECTIONS IN TYPE 1 DIABETES

by

Sima Sapkota

A project

submitted in partial fulfillment of the requirements for the degree of

Doctor of Nursing Practice

California State University

Northern California Consortium Doctor of Nursing Practice (NCCDNP)

May, 2018

APPROVED

For the California State University, Northern Consortium
Doctor of Nursing Practice:

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ACKNOWLEDGMENTS

I would like to acknowledge and thank my project chair Dr. Alice Butzlaff who has supported and guided me throughout this project. Her assurance and positive outlooks made this journey rewarding and enjoyable. I want to thank my mentor, Dr. Patricia Ostrander. She has provided me constant support, inspiration and guidance throughout my doctoral educational journey. Her confidence and endless support gave me strength to accomplish this project. I would also like to thank my other committee member, Annette Dreith for her support, enthusiasm, and guidance throughout the project.

I would like to thank Dr. Sylvia Miller, who has been my faculty, mentor, advisor, and cheerleader throughout the program. I also want to thank all the other faculty members for sharing their lifetime learning experiences during this program. I want to acknowledge my DNP cohort whose support and encouragement made this journey much more enjoyable and helped us to succeed as a team.

At the end, I would like to thank my family for their encouragement and love. My husband, Santosh, has supported me throughout this journey. My children Savya and Srisha have been very patience with me during this program. I would also like to thank my parents for their unconditional love, and constant support for my life-long educational quests.

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CHAPTER 1: INTRODUCTION

According to the Centers for Disease Control and Prevention (CDC, 2014) patients with diabetes account for approximately 29.1 million people, or 9.3% of the total population. Of these, an estimated 8.1 million people remain undiagnosed, which results in delays in treatment, increased risk of complications, and increased health care costs. The estimated diabetes mellitus (Type 1 or Type 2) related cost in the United States is increasing. In 2012, diabetes related total costs were $245 billion (CDC, 2014). Medical related costs comprised $176 billion, and $69 billion was related to disability, work loss, and premature death of patients. In fact, the CDC (2014) estimates that overall medical expenses were 2.3 times more for people with diabetes than those without diabetes.

Despite investment in better diabetes prevention and care, diabetes mellitus is still the seventh leading cause of death in the United States (CDC, 2014). A large clinical trial, Diabetes Control and Complications Trial (DCCT) conducted over 10-years showed better control of diabetes, delayed the progression of micro and macro vascular complications (Nathan et al., 1993). Clients involved in the clinical trial had delayed disease progression when insulin therapy was used to improve glycemic control. It is therefore vital to improve glycemic control of patients with diabetes mellitus to reduce long-term complications and premature death.

Background and Significance

Type 1 Diabetes

Type 1 diabetes is an autoimmune disease which causes destruction of beta cells in the pancreas leading to lack of insulin production. Insulin is necessary for the body to maintain stable blood glucose levels. Therefore, in type 1 diabetes, exogenous insulin administration is the most important part of disease management (American Diabetes Association [ADA], 2016).

Exogenous insulin delivery may fall into two different regimens: insulin pump therapy (IPT) or multiple daily insulin injections (MDII). Diabetes is a chronic condition which requires essential life-long self-care behaviors. These behaviors promote positive outcomes such as healthy eating, physical activity, blood sugar monitoring, medication compliance, problem-solving skills, healthy coping skills and risk-reduction behaviors (Shrivastava, Shrivastava, & Ramasamy, 2013).

Problem Statement

There is not enough data to establish a conclusive result that demonstrates the effectiveness of IPT in comparison to MDII in adult patients with type 1 diabetes. Many studies have suggested that IPT has improved glycemic control in adults with type 1 diabetes; however, its clinical impacts and other variables are not clear (Raskin, Bode, & Marks, 2003). Moreover, prior studies have been conducted mostly in pediatric populations or in type 2 diabetes populations (Nabhan et al., 2008). The desired outcome of this project is to generate the data, which will result in statistically significant values to determine the most effective treatment method for insulin delivery in this sample population.

Purpose

The purpose of the study was to compare the retrospective data of A1C and BMI of patients with type 1 diabetes after they transition from MDII to IPT. The goal was to evaluate the data for gap analysis to determine the most effective method of insulin delivery in a population with type 1 diabetes.

Hypotheses

1. There will be an improvement in the A1C of adult patients with type 1 DM after transitioning from MDII to IPT.
2. There will be an improvement in the BMI of adult patients with type 1 DM after transitioning from MDII to IPT.

CHAPTER 2: LITERATURE REVIEW

Diabetes is a chronic disease that requires continual monitoring and interventions. A review of the literature was undertaken to review study variables. Variables selected included IPT, MDII, hemoglobin A1c (A1C) and BMI. The A1C test is a blood test that gives an average blood glucose reading for the past three months. A1C below 7% is a target goal for diabetes management (ADA, 2016). Body mass index (BMI) in kilograms per meter squared, is a measure of body fat based on height and weight that applies to adult men and women. BMI is used to indicate if patient is overweight, obese, underweight or normal. A healthy BMI score is between 20 and 25 kg/m2 (ADA, 2016).

Hermanides and colleagues (2011) conducted a multinational, multi-center randomized controlled clinical trial over 18-months to investigate the efficacy of sensor-augmented IPT vs. MDII therapy in patients with suboptimally controlled type 1 diabetes. The trial was completed by 43⁄44 (98%) patients in the sensor-augmented IPT group and 35⁄39 (90%) patients in the MDII group. The primary outcome measure, a change in A1C, was analyzed using an ANCOVA model. The differences in proportions of patients reaching A1C < 7% and experiencing a severe hypoglycemic episode was calculated using chi square analyses. Mean A1C at baseline and at 26 weeks changed from 8.46% to 7.23% in the sensor-augmented IPT group and from 8.59% to 8.46% in the MDII group. Mean difference in change in A1C after 26 weeks was 1.21% ($P < 0.001$) in favor of the sensor-augmented IPT group. Although this study has few limitations, this study results showed reduction of A1C in group with insulin delivery by IPT.

A prospective chart review by Boucher-Berry and colleagues (2016) was undertaken to discern whether the basal insulin dose or the bolus insulin dose added the most weight gain associated with insulin therapy. In this quantitative research study, researchers looked deeper

into IPT and the association with weight gain and BMI. Quantitative data such as A1C, height, weight, BMI, and tanner stage were collected from the one-year data from a total of 91 patients who were transitioned from basal-bolus regimen to IPT. Among them, 54 were female and 37 were male patients between 2.3–17.8 years of age. Patients were divided into two groups based on changes in BMI: Group 1 (no change or decrease) and Group 2 (increase). The type of analysis was t-test and chi square (X 2) analyses. The two groups had similar total daily dose (TDD), (0.9 ± 0.2 vs.0.8 ± 0.2 U/kg/day), however Group 1 had a higher bolus: basal insulin ratio (1.8 ± 0.6 vs. 1.5 ± 0.6, $p < 0.05$). While Groups 1 and 2 had similar A1C values (7.7 ± 0.7 vs. 7.70 ± 0.6 %; $p = 0.79$).

Investigators concluded that even though the total insulin doses per kilogram of body weight remained same, the group that experienced the weight gain had a significantly higher basal insulin dosage than the other group. Findings suggests that the basal insulin dose is more of a contributor to the weight gain than the total insulin dose. The implication of this study was to reduce bolus and basal insulin doses during insulin to avoid excess weight gain (Boucher-Berry, et al., 2016).

Alamoudi and colleague (2017) conducted a study to compare glucose profiles in patients with T1DM who were on IPT or MDII and decided to fast for Ramadan. Glucose data from self-monitoring of blood glucose and continuous glucose monitoring were compared in the two groups. Researchers assessed glucose control by measuring serum fructosamine levels. Fructosamine level represents a measure of glycation of proteins in the plasma glucose. It reflects the average levels of blood glucose during the former 2-3 weeks (Danese, et al., 2015). A total of 156 patients participated in the study. Among them 61 were on IPT and 95 were on MDII.

The result of the study suggested that there was no difference in glycemic control in both groups as measured by fructosamine. Even though glucose variability was significantly better in the IPT group (SMBG; standard deviation [SD] 66.9 ± 15.3 vs. 76.9 ± 29.9, $P = 0.02$) (CGM; SD 68.1 ± 19.6 vs. 78.7 ± 24.9, $P = 0.04$), there was no difference in glycemic control (Alamoudi, et al., 2017).

Karges and colleague (2017) conducted a population-based cohort study between 446 diabetes centers participating in the Diabetes Prospective Follow-up Initiative in Germany, Austria, and Luxembourg. Researchers identified patients with type 1 diabetes younger than 20 years and diabetes duration of more than 1 year. Researchers also compared the insulin dose, A1C level and BMI in two groups.

Among 30579 patients with mean age of 14.1 years, 14119 used IPT and 16460 used MDII. The IPT group had lower A1C levels than with MDII (8.04% vs 8.22%; difference, -0.18 [95% CI, -0.22 to -0.13], $P < .001$). Even though total daily insulin doses were lower for IPT group compared to MDII group, there was no significant difference in BMI between both treatment regimens (Karges, et al., 2017). Investigators concluded that the children, adolescents, and young adults with type 1 diabetes who used IPT had improved clinical outcomes as compared to patients who used MDII.

AbdulRasoul and colleague (2015) conducted a retrospective comparative study of IPT and MDII therapy in a large cohort of pediatric patients with type 1 diabetes in Kuwait. Data on 326 patients who were started on IPT were retrospectively compared with those of 326 patients on MDII. They were matched for sex, age at diagnosis, duration of diagnosis, glycemic control, insulin requirement, and BMI. Data was collected for A1C, and insulin dose, at baseline and every three months.

The researchers found that the A1C decreased in both groups in the first year. However, A1C decrease was most significant in the IPT group compared to the MDII group in the first year and remained lower for IPT group throughout the study period. After the second year A1C levels in the MDII group gradually increased again to values higher than those measured at baseline (8.9±1.7 at baseline vs. 9.0 ± 1.2 in the fifth year, $p<0.001$). The difference in the A1C values at baseline and in the fifth year in the IPT and MDII group were 8.9±1.4 and 8.3±1.2 vs. 8.8±1.4 and 9.0±1.6, respectively; $p<0.05$). BMI increased significantly for both groups at the end of the fifth year. There was no difference in the rate of diabetic ketoacidosis in either group. The IPT group had more severe hypoglycemic episodes at baseline but improved overtime.

Ziegler and colleagues (2013) conducted a prospective, randomized, controlled, multinational study to evaluate the impact of using an insulin bolus advisor embedded in a blood glucose meter on glycemic control and treatment satisfaction in patients using MDII therapy. A total of 218 MDII-treated patients with poorly controlled diabetes (n=202 with type 1 diabetes, n=16 with type 2 diabetes) who were 18 years of age or older, were enrolled in a 26-week study. Participants had mean baseline A1C of 8.9% (SD, 1.2), and mean BMI of 26.5 kg/m2 (SD, 4.2).

The study was designed to have 90% power to detect a mean difference of 0.5% change in A1C levels between two groups from baseline to study end in favor of the experimental group. This was determined using a one-sided, two-sample t test ($\alpha = 0.05$) assuming a common SD of 0.9% for the intention-to-treat population. Pearson correlation coefficients were computed for the A1C values and all other variables of interest. A total of 193 patients (Control n = 93; Experimental n = 100) completed the study. Significantly more experimental patients achieved >0.5% A1C reduction (56.0% vs. 34.4%; $P < 0.01$). A potential limitation of the study design

was both groups had received intensified diabetes care, which may explain why significant improvements were seen in both study groups (Ziegler et al., 2013).

In this qualitative research study by Ferrari, Mcilwain, and Ambler (2016) children's experience of different insulin regimens were studied. In this study, interviews with 17 children at two time points were analyzed; once on MDII, and again 4 months later after some subjects started IPT. Insulin pump therapy allowed children to listen to and trust their bodily cues rather than override cues. At the follow-up interview, eight children had transitioned to using insulin pump therapy for at least 3.5 months, and the remaining nine children were still using MDII. The conclusion of this study is that the children felt the insulin pump increased their flexibility in diet (Ferrari, Mcilwain, and Ambler, 2016).

The study done by Wilkinson and his colleagues (2010) suggested that even though the use of insulin pump therapy increased, the patients with type 1 diabetes continued to have suboptimal control of diabetes (Wilkinson, et al., 2010). Researchers have concluded IPT can be an effective therapy for both children and adolescents, however just wearing the IPT are not sufficient to achieve the glycemic goal. Investigators found that it was important for patients to engage in self-care behaviors to achieve glycemic goal (Wilkinson, et al., 2010).

Aronson and colleagues (2016) compared the efficacy of IPT and MDII in patients with type 2 diabetes. A total of 331 patients with A1C levels $\geq$8.0% and $\leq$12% were randomized to IPT or continued MDII for 6 months (randomization phase). During a 6-month continuation phase (CP), the MDII group was also subsequently switched to IPT. The researchers looked at the between-group difference in change in mean A1C from baseline to the end of the randomization phase (Aronson, et al., 2016).

The mean A1C at baseline was 9% in both groups. At the end of the randomization phase, the reduction in A1C was significantly greater with IPT than with MDII (−1.1±1.2% vs −0.4±1.1%; $p<0.001$). The IPT group maintained this improvement to 12 months. The MDII group, which was switched to IPT also showed a 0.8% reduction in A1C. The final A1C level was same in both groups. There were no differences in BMI or ketoacidosis between groups. Researchers concluded that IPT had a durable effect on glycemic control in uncontrolled type 2 diabetes patients (Aronson, et al., 2016).

Ackermann and colleagues (2017) conducted a study to evaluate blood glucose control for patients with diabetes who transitioned from MDII to IPT. The design of the study was pre-post with propensity-matched comparison. The study participants had insulin-requiring diabetes and were commercially insured US adults, aged 18-64 years. They transitioned from MDII to IPT between July 1, 2009, and June 30, 2012 (IPT initiators = 2539), or who continued using MDII (n = 2539). Mean A1C, healthcare encounters for hypoglycemia, and direct medical expenditures were collected from the medical claims and laboratory results files obtained from a large US-wide healthcare payer.

To compare A1C and healthcare expenditures for 3 years following the switch to IPT, the researchers had utilized difference-in-differences regression models (Ackermann, et al., 2017). Researchers found that IPT initiators had lower mean A1C concentration by 0.46% in year 2 (P = .0003) and by 0.32% in year 3 (P = .047). IPT users also had a higher rate of hypoglycemia episodes in year 1 (P = .002). However over 3 years, mean per-person total healthcare expenditures were $20,565 more/per-person for IPT users compared with matched MDII patients. Researchers concluded that transitioning from MDII to IPT was related with some

improvements in A1C but more hypoglycemia encounters and increased healthcare expenditures, for adults with insulin-requiring diabetes (Ackermann, et al., 2017).

Summary of Literature Reviews

The conclusion from the literature review was that the majority of the studies suggested use of IPT when compared to MDII showed better A1C in patient with insulin requiring diabetes (AbdulRasoul, et al., 2015; Aronson, et al., 2016; Ackermann, et al., 2017; Hermanides et al., 2011; Karges, et al., 2017). Result of other studies suggested use of IPT when compared to MDII showed no statistically significant difference in A1C (Alamoudi, et al., 2017 and Boucher-Berry, et al., 2016).

Lecture review revealed that even though total daily insulin doses were lower for IPT group compared to MDII group, there was no significant difference in BMI between both treatment regimens (AbdulRasoul, et al., 2015 and Karges, et al., 2017). Other studies suggested BMI increased significantly for both MDII and IPT groups in comparison to their baseline BMI but there was no difference in BMI between two treatment regimens (AbdulRasoul, et al., 2015; Boucher-Berry, et al., 2016; and Karges, et al., 2017). In a conclusion there was no difference in BMI between MDII and IPT group.

CHAPTER 3: METHODOLOGY

Study Design

The design of this research study was a retrospective cross sectional study via chart review. A total of 58 patients with type 1 diabetes seen in 2017 at a Sacramento Endocrinology group who transitioned from MDII to IPT were selected. Patient's pre-insulin pump data such as A1C and BMI was compared to post-insulin pump therapy over 3-time points. The independent variable in this study was pre-IPT and post-IPT. The dependent variables were A1C and BMI.

Research Questions

1. (a) Is there a difference in the A1C of adult patients with type 1 DM after transitioning from MDII to IPT?

   (b) Is there a difference in the BMI of adult patients with type 1 DM after transitioning from MDII to IPT?

2. (a) Is there a relationship between A1C of patients with type 1 DM after transitioning from MDII to IPT?

   (b) Is there a relationship between BMI of adult patients with type 1 DM after transitioning from MDII to IPT?

Method

The method of the study was a quantitative approach, retrospective, cross sectional, non-experimental, and descriptive design. The data were collected by retrospective chart review. Patients were identified by utilizing the electronic database. Patients were selected for the study by inclusion criteria. Patients who met the exclusion criteria were removed from the study. The total population who met all criteria composed the population of interest.

Population and Sample Selection

Demographic data including patient age and gender was collected. A convenience sample was selected by inclusion and exclusion criteria. The inclusion criteria included adult patients, 18-85 years of age, with type 1 DM, who used MDII for at least one year before transitioning to IPT. Patients needed to be on IPT for at least one year. Exclusion criteria included patients who have been admitted more than two times in a year due to the severe disease complication diabetes ketoacidosis (DKA) and non-adherence defined by three consecutive cancellations of appointments, and patients with type 2 diabetes.

Settings and Data Collection

The study took place in one of the clinics in the endocrinology department of a large Northern California medical group. The department cares for a total of 273 adult patients with type 1 diabetes. Electronic data collection technology was utilized to collect the information of the patient's age, gender, BMI, and A1C. Data were collected before and after patient transition to IPT at 3, 6, and 12 months post-IPT. Timeframe of data collection for each patient using IPT was differ, as each patient had started the IPT at different time.

Protection of Human Subjects

To assure protection of patient confidentiality and human rights, the Institutional Review Board (IRB) at Dignity Health Medical Foundation and the IRB at Fresno State University approved this project. Subjects were de-identified by an information technology specialist who randomly assigned an identification number before data collection took place. Only data variables under study were collected from patient records and placed on electronic spreadsheets. Spreadsheets were saved within a locked and coded computer. The researcher was the only

individual who conducted the chart review to gather the data from the patients' electronic medical records.

Theoretical Framework

Orem's self-care deficit nursing theory was utilized to guide this research. The theory of self-care was directly applicable to the patient with diabetes. Self-care deficit theory has been tested, researched, and published in the literature (Orem et al., 2003). Orem believed the self-care action the maintenance of human functioning such as the continuance of life, health, and well-being were possible. Even though, these actions have been routine and spontaneous, they were driven by the functional needs of human beings (Orem et al., 2003).

The concept of the self-care theory explains that every individual thrived and recovered faster by participating in their self-care as much as possible. Self-care theory has been relevant to diabetes self-management and has been directly applicable to diabetes care. Self-management skills are essential for the quality of life for patients with diabetes (Mensing & Cornell, 2014) in the context of both IPT and MDII. Designing an effective intervention to help patients with diabetes reach A1C and BMI goals was the focus of this research project.

Data Analysis

The data were analyzed using the IBM® SPSS (Statistical Package for the Social Sciences). Descriptive statistics (means, standard deviations, frequencies) for all study variables were obtained. Bivariate correlations between A1C and BMI measurements were conducted. The Pearson correlation coefficient test was conducted to analyze the relationship of A1C and BMI. Two repeated measures ANOVAs were conducted within subjects for both A1C and BMI. Repeated measure ANOVA was utilized to examine differences within subjects after starting IPT. Level of significance was established at $p = 0.05$.

CHAPTER 4: RESULTS

A total of 114 patients' charts were reviewed and 58 were selected for the study based on inclusion and exclusion criteria. The mean age of the sample was 46 (minimum age 21, maximum age 80). Over half of the subjects were female (51.7% female, 48.3% male). Bivariate correlations reveled that there were a significant relationships between all four A1C measures. There were significant relationships between all four BMI measures. However, there were no significant relationships between any A1C and BMI measurements (see Table 1).

Table 1

Pearson Correlations Between A1C and BMI Measurement Overtime

Variables	1	2	3	4	5	6	7
1. A1C Baseline	-						
2. A1C 3 Months	.73**	-					
3. A1C 3-6 Months	.80**	.76**	-				
4. A1C 6-12 Months	.74**	.68**	.90**	-			
5. BMI Baseline	-.20	-.03	-.07	-.08	-		
6. BMI 3 Months	-.11	-.04	.02	-.01	.98**	-	
7. BMI 3-6 Months	-.09	-.07	.04	-.01	.97**	.98**	-
8. BMI 6-12 Months	-.10	.09	.03	-.02	.96**	.98**	.99**

Note. ** $p<.01$

Baseline mean A1C was 8.31% and 3 months, 6 months and 12 months post-pump A1C were 7.75%, 7.86% and 7.9% respectively. A statistically significant difference was found across the four time period measurements of A1C in adult patients with type 1 DM after transitioning from MDII to IPT over time F (2.32, 130.13)= 6.82, p <.01. Post hoc revealed that there was a statistically significant difference between the base line A1C and post-IPT A1C. There was a statistically significant difference between baseline A1C to 3 months (p <.01), and 3-6 months (p <.01) post-IPT A1C. There was no significant difference between mean baselines A1C to 12 months post-IPT A1C level. Mean A1C had decreased from baseline to 3 months and 3-6 months post-IPT but stayed relatively stable after 12 months (see Table 2). Figure 1 shows the line graph of these measurements.

Table 2

Repeated Measures ANOVA Results for A1C and BMI

Variables	M	SD	Df	F	p	η^2
A1C			2.32,130.13	6.82	.001	.11
Baseline	8.31	1.73				
3 Months	7.75	1.03				
3-6 Months	7.90	1.32				
6-12 Months	7.90	1.32				
BMI			2.02,113.50	3.70	.03	.06
Baseline	27.95	5.99				
BMI 3 Months	28.42	5.70				
BMI 3-6 Months	28.41	5.78				
BMI 6-12 Months	28.34	5.78				

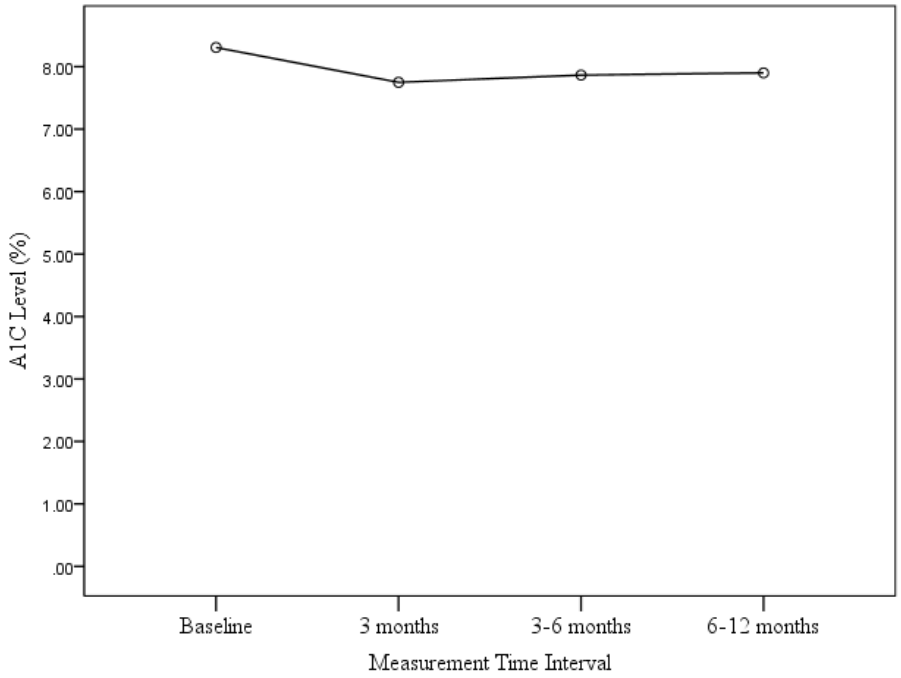

Figure 1. Line graph showing A1C measurement over the four-time periods.

There was a significant difference across the four time period measurement of BMI in adult patients with type 1 DM after transitioning from MDII to IPT over time F (2.02, 113.50)= 3.70, p<.05. Baseline mean BMI was 27.95 kg/m2 and 3 months, 6 months and 12 months post-IPT BMI were 28.42 kg/m2, 28.41 kg/m2, and 28.38 kg/m2 respectively. Post hoc revealed that there was a statistically significant (p< .04) difference between baseline BMI and 3 months post-IPT BMI. BMI increased from baseline to 3 months post-IPT but stayed relatively stable after 3-6 months and 12 months (see Table 2). Figure 2 shows the line graph of these measurements.

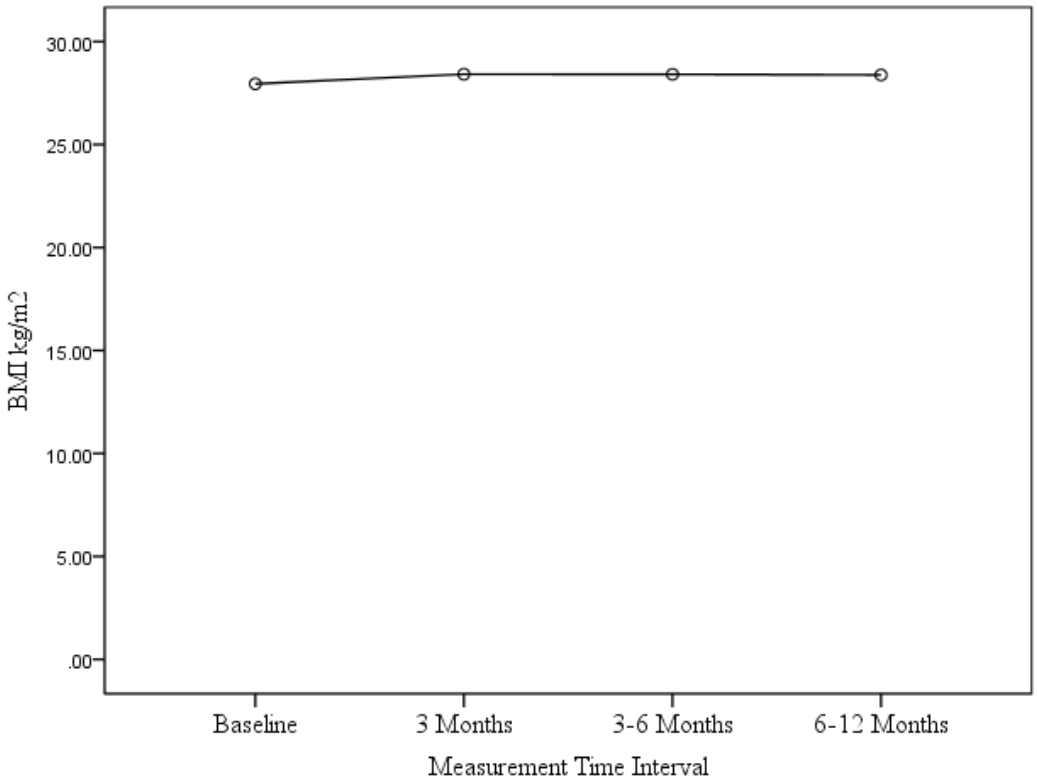

Figure 2. Line graph showing BMI measurement over the four-time periods.

CHAPTER 5: DISCUSSION

The first hypothesis stated there will be an improvement in the A1C of adult patients with type 1 diabetes after transitioning from MDII to IPT. This study showed an improvement in the A1C of adult patients with type 1 diabetes after transitioning from MDII to IPT. There was a significant difference across the four time periods in the measurement of A1C in adult patients with type 1 diabetes after transitioning from MDII to IPT. Post hoc analysis was done to find out where the actual difference was observed in A1C in those four time period measurements. It was found that the actual difference was observed between the baseline A1C to 3 months post-IPT A1C and baseline A1C to 3-6 months post-IPT A1C. Mean A1C decreased significantly from baseline (M=8.31%, SD= 1.73) to 3 months (M=7.75%, SD= 0.14) and 3-6 months post-pump period (M=7.86%, SD= 0.18). There was no difference in mean A1C from baseline to 12 months post-IPT. Findings revealed results similar to those found in previous literature review (Alamoudi, et al., 2017 and Boucher-Berry, et al., 2016; Wilkinson, et al., 2010).

The second hypothesis was that there will be an improvement in the BMI of adult patients with type 1 diabetes after transitioning from MDII to IPT. This study did not support the hypothesis as the results did not show any improvement in the BMI of adult patients with type 1 diabetes after transitioning from MDII to IPT. There was a significant difference across the four time period measurements of BMI after transitioning from MDII to IPT. Post hoc analysis was done to find out where the actual difference was observed in BMI in those four time period measurements. Mean BMI increased significantly from baseline (M=27.9502 kg/m2, SD= 6.0) to 3 months post-IPT (M=28.4175 kg/m2, SD= 5.7). However, there was no difference in mean BMI from baseline to 3-6 months and baseline to 12 months post-IPT. Findings revealed results

similar to those found in previous literature review (AbdulRasoul, et al., 2015 & Karges, et al., 2017).

There was not any relationship between A1C and BMI in patients with type 1 diabetes. There were significant positive relationships between all four times period measurements of A1C in adult patients with type 1 diabetes. There were also significant positive relationships between all four times period measurements of BMI in adult patients with type 1 diabetes.

The conclusion was that the use of IPT when compared to MDII demonstrated a statistically significant improvement in A1C for 3 months and 3-6 months post pump but the improvement did not sustain overtime. Some reviewed studies suggested use of IPT when compared to MDII showed better A1C (AbdulRasoul, et al., 2015; Aronson, et al., 2016; Ackermann, et al., 2017; Hermanides et al., 2011; Karges, et al., 2017) but other studies suggested no statistically significant difference in A1C between two groups(Alamoudi, et al., 2017 and Boucher-Berry, et al., 2016). Also, BMI increased significantly from baseline to 3 months post pump and remained the same throughout the period. There was no difference between baselines BMI to 12 months post-IPT BMI. Findings revealed results similar to those found in previous research investigations reported in the literature review (AbdulRasoul, et al., 2015; Boucher-Berry, et al., 2016; & Karges, et al., 2017).

Most of the times, among the sample population, improved A1C levels were observed after patients transitioned to IPT from the MDII. Therefore, A1C was expected to remain lower after transitioning to IPT. However, that was just an assumption as there was no prior study done with this patient population to measure the difference in A1C after patients transitioned to IPT from MDII. In this study patient had lower A1C for 3 months and 3-6 months after transiting to IPT which was expected finding but A1C not remaining lower was unexpected. It is possible that

in the beginning of the transition from the MDII to IPT, patients might have been more active in managing their blood sugars after the initiation of new form of insulin delivery. It may also be due to dietary control or accurate carbohydrate counting while using the IPT.

In this study, patients initially gained weight after transitioning from MDII to IPT but there was no difference between base line BMI to 12 months post-IPT BMI , which is consistent with the literature reviewed (Boucher-Berry, et al., 2016; AbdulRasoul, et al., 2015). It is possible that patients might have gained weight because they did not have much glycosuria due to better glycemic control. However it was expected that BMI will improve with IPT use because patients use less insulin while on IPT than MDII.

Finally, hypoglycemia was not assessed due to inconsistent or lack of recorded data within the patient chart. One of the challenges of managing type 1 diabetes is the need to control hyperglycemia and hypoglycemia (Pavlicek, 2015). Findings regarding the relationship between A1C and hypoglycemia has been controversial. Some literature suggests that the IPT group had significantly lower rates of severe hypoglycemia compared to MDII (Karges, et al., 2017). However, other research studies suggest that the reduction in A1C could be related to frequent hypoglycemia as IPT group had more hypoglycemia than MDII (Ackermann, et al., 2017; Wainstein, et al., 2005). Moreover, many research studies did not find any difference in hypoglycemia rate between IPT and MDII (Hermanides, et al., 2011; Alamoudi, et al., 2017, Zigler, et al., 2013). Investigating the AIC with recorded incidence of hypoglycemia may also influence IPT results.

Limitations of the Project

Selection. In this study patients were not randomly selected; one of the threats to internal validity is self-selection biases. Self-selection biases result in pre-existing differences between groups (Polit, & Beck, 2008). There is always a risk that the groups are nonequivalent, so the outcome may result from the initial differences rather than the effects of independent variables. However, convenience samples are often used in medical research.

Non experimental design. Using a non-experimental design can limit control of other variables such as diet and exercise. Diet and exercise play an important role in glycemic control; therefore, it is important to incorporate data on diet and exercise. Diet and exercise regimen may vary between individuals and this was not controlled in the current study. Self-reported diet and exercise measures were considered, however, they do not have high validity.

Maturation. Maturation in a research context means the processes that include physical growth, emotional maturity, fatigue, or disease burn out (Polit, & Beck, 2008). The length of the current study was 12 months, and there was a slight threat to internal validity related to maturity. The outcomes of the study may have been influenced by the amount of time a patient has been diagnosed with diabetes. For example, patients who have had diabetes for many years might have a different level of expertise with the self-management of their disease than those who are newly-diagnosed. The efficacy of IPT in young T1DM adults was worse than in older patients, which could be due to age-dependent behaviors, social environment, or both (Grzanka, et al., 2012). On the other hand, patients with long histories of diabetes may suffer from disease burn out, which may result in low adherence to self-managing their disease.

Conclusion

Managing diabetes is a challenge. Reaching target A1C levels and BMI goals can be used as standard measures, however good control of diabetes requires good A1C with no or minimal hypoglycemia rates. Therefore, it is crucial for clinicians to also monitor and record hypoglycemia rates along with A1C and BMI.

In addition, IPT is not accessible to all populations. IPT is expensive and most insurance policies do not fully cover the insulin pump and supplies. Although this study supported IPT use, it also showed only a short-term reduction of AIC and BMI when initiating the pump. What has become clear is for this sample during the transition from MDII to IPT elevations of A1C did not occur.

It is important for the clinician to consider the individual when planning a transition to IPT. Clinicians need to consider individual patient preferences about using IPT in patients with type 1 diabetes. It is also important to engage in self-care behavior to achieve glycemic goal. Better glycemic control and prevention of disease-related complications are the goals of diabetes management. Designing effective interventions to help patients with diabetes reach AIC and BMI goals are the focus of the diabetes management, whether or not it is reached by the IPT or MDII.

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APPENDICES

APPENDIX A: DIGNITY HEALTH, MERCY MEDICAL GROUP IRB APPROVAL

Federal Wide Assurance (FWA) #00001499
Dignity Health IORG0001540

Date: November 01, 2017

IRB: Dignity Health Sacramento Regional IRB #00006573
3400 Data Drive
Rancho Cordova, CA 95670

To: Sima Sapkota

IRB #: SAC-2017-293
Study Title: The Effectiveness of Insulin Pump Therapy in comparison to Multiple Daily Insulin Injections in Type 1 Diabetes

IRB Submission: Initial Review Submission Form
Reference #: 018922

Review Cycle: 12 Months
Approval Expiration Date: 10/29/2018

IRB Review Type: Expedite: Category 5 - Data/specimens collected for non-research purposes
IRB Review Date: 10/30/2017 **IRB Decision:** Approved

The Institutional Review Board (IRB) reviewed and **approved** your new protocol submission including the documents listed in Appendix 1. Study was approved with waiver of informed consent and HIPAA.

Please be sure you have received a final administrative approval letter prior to implementing your study.

If you expect to encounter a study-participant population of non-English speaking persons, please be reminded to submit certified translation(s) of the approved consent and/or authorization document(s) in the appropriate language for IRB review and approval.

As principal investigator for the above referenced study, you are responsible for the following:

- Adherence to applicable Federal regulations, Dignity Health policy and the policies of this Institutional Review Board.
- Supervision and responsibility for all investigators and research team members engaged in research covered by this IRB; ensure all licensed study personnel act within their scope of

practice and, if applicable, their medical staff credentials; and non-licensed personnel act within their job description and facility policies and guidelines.

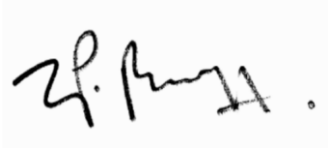
- Responsible for using the current IRB approved consent form (if applicable).
- Record keeping of all activities including documentation of informed consent when applicable.
- Promptly reporting all internal adverse events according to Dignity Health and IRB guidelines.
- Promptly reporting external adverse events according to Dignity Health and IRB guidelines.
- Promptly reporting any deviations from the protocol or consent process (including 'emergency' enrollment).
- Promptly reporting any new unanticipated risks or new information that may impact the protocol, study participants or others.
- Promptly reporting all study management correspondence with regulatory agencies and sponsors including administrative actions.
- Promptly reporting DSMB reports when received and/or available.

- Submission of a periodic progress/renewal report no less than annually to the IRB. The IRB has designated that it will review this protocol every **12 Months**. Progress Reports must be received and approved prior to expiration date to allow continuing enrollment and/or data collection.
- Reporting of any changes to this study including; protocol, consent, application, investigators, and study staff **prior** to implementation. (Changes necessary to eliminate immediate hazards to participants may be implemented prior to IRB approval.)
- Submission of a study closure report within 30 days of the study's completion.

The IRB and Dignity Health maintains the authority to terminate or suspend approval of research that is not being conducted in accordance with Federal regulations and Dignity Health policies and procedures or research that has been associated with unexpected serious harm to participants.

If you have any questions or need further assistance please contact the Dignity Health Sacramento Regional IRB at (916) 453-4012 or by e-mail to Brenda.Cobb001@DignityHealth.org or Russell.Stolp@DignityHealth.org.

Sincerely,



Jeffrey Braff, DrPH
IRB Chair

(This has been electronically signed)

Submission Components			
Form Name	Version		Outcome
Initial Review Submission Form	Version 1.0		Approved
Dignity Health Internal IRB Application	Version 1.0		Approved
Study Document			
Title	Version #	Version Date	Outcome
Conflict of Interest form	Version 1.0	08/29/2017	Acknowledged
Study Protocol	Version 1.0	09/06/2017	Approved
Data Elements Excel spread sheet	Version 1.0	09/06/2017	Acknowledged
Department approval form	Version 1.0	08/25/2017	Acknowledged
CITI training	Version 1.0	08/25/2017	Acknowledged
CV-Sima Sapkota	Version 1.0	08/25/2017	Acknowledged
Resource Consumption Worksheet	Version 1.0	08/25/2017	Acknowledged

Appendix 1

Dignity Health is organized and operates according to its Federal Wide Assurance with the Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP). Dignity Health IRBs operate in compliance with the Code of Federal Regulations (CFR) including 45 CFR 46, 21 CFR 56 and 21 CFR 11.
(Revised 04/01/2016)

APPENDIX B: CALIFORNIA STATE UNIVERSITY IRB APPROVAL

FRESNO STATE
College of Health and Human Services

California State University,
Fresno School of Nursing
IRB Approval

November 15, 2017

RE: DNP1721 The Effectiveness of Insulin Pump Therapy in comparison to Multiple Day Insulin Injections in Type 1 Diabetes

Dear Sima Sapkota,

As the Chair of the Department of Nursing Research Committee, serving as the Institutional Review Board for the Department of Nursing, I have reviewed and approved your review request for the above-referenced project for a period of 12 months. I have determined your study to meet the criteria for Minimal Risk IRB review.

Under the Policy and Procedures for Research with Human Subjects at California State University, Fresno, your proposal meets minimal risk criteria according to section 3.3.7: Research in which the risks of harm anticipated are not greater, probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The Research Committee may periodically wish to assess the adequacy of research process.
If, in the course of the study, you consider making any changes in the protocol or consent form, you must forward this information to the Research Committee prior to implementation unless the change is necessary to eliminate an apparent immediate hazard to the research participant(s).

This study expires: November 15, 2018

The Research Committee is authorized to periodically assess the adequacy of the consent and research process. All problems having to do with subject safety must be reported to the Research Committee. Please maintain proper data control and confidentiality.

If you have any questions, please contact me through the CSU, Fresno School of Nursing Research Committee at symiller@csufresno.edu.

Sincerely,

Sylvia Miller

Sylvia Miller EdD, RN, FNP-C
School of Nursing, Research Committee, Chair

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APPENDIX C: DEFINITION OF TERMINOLOGY

HbA1C: HbA1C test is a blood test that reflects average blood glucose levels over the past 3 months. The HbA1C test is also called the hemoglobin A1C, A1C, HbA1c, glycated hemoglobin, or glycohemoglobin test.

BMI: Body mass index (BMI) in kilograms per meter squared, is a measure of body fat based on height and weight that applies to adult men and women. BMI is used to indicate if patient is overweight, obese, underweight or normal. A healthy BMI score is between 20 and 25 kg/m2.

Hypoglycemia: Hypoglycemia, also known as low blood glucose is a condition characterized by abnormally low blood glucose (usually less than 70 mg/dl), which in extreme cases can lead to unconsciousness and death.

Insulin Pump Therapy: is a continuous subcutaneous insulin infusion through a pump that delivers insulin continuously under the skin through a small plastic tube and cannula. Pumps are filled with rapid acting insulin to supply both background insulin and mealtime insulin.