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Comparison of Quality of Life in Diabetics Using Insulin Injection Therapy versus Subcutaneous Insulin Infusion Therapy

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Comparison of Quality of Life in Diabetics Using Insulin Injection Therapy versus
Subcutaneous Insulin Infusion Therapy

by

Katie Michele Reynolds

Thesis

Submitted to the Department of Health and Human Services

Eastern Michigan University

in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

in

Human Nutrition

Thesis Committee:

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July 5, 2007

Ypsilanti, Michigan

Dedication

This thesis is dedicated to my Dad, who taught me that we are not born intelligent, we are only as smart as we choose to be, and that a laugh can make even the most stressful task an easy one. It is also dedicated to my Momma, who taught me that unconditional love is one of the few things we need to be inspired. Last, to my fiancé, Tommy, who gave me endless support and encouragement to complete my Masters degree. I love you all more than any dedication could explain.

Acknowledgements

Dr. Anahita Mistry has been a wonderful thesis supervisor. Her advice, insightful criticisms, and dedicated support of this project were greatly needed and deeply appreciated. I would also like to thank Dr. Judi Brooks and Joan Lundblad, whose encouragement aided the writing of this thesis in innumerable ways. Last, I would like to thank Dr. Sushma Reddy for all her help with this thesis. Without her, this could have never been completed.

Abstract

Comparison of Quality of Life in Diabetics Using Insulin Injection Therapy versus Subcutaneous Insulin Infusion Therapy

The goal of this study was to determine the effectiveness of insulin delivered via multiple injections or by infusion via a pump on the quality of life in adult insulin-dependent diabetics. Four parameters, namely hemoglobin A1C (3 month average blood sugar levels), self-reported healthy eating habits demonstrated by consumption of 3 meals/3 snacks everyday, frequency of exercise of daily 30 min or longer duration and opinion of quality of life, were evaluated in patients receiving either insulin injections or infusion.

Pump users reported enhanced eating and exercise behaviors and feeling in good health, compared with patients receiving injections. In contrast, hemoglobin A1C was lower (6.9 ± 0.9 %) in patients receiving insulin injections compared with those receiving infusions (7.9 ± 0.6 %). Pump wearers perceived that they had a better quality of life, but their glycemic control was not necessarily improved compared to those on insulin injections.

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Chapter 1

Introduction and Research Statement

Introduction

Aretaeus was a Greek physician from Cappadocia who practiced in Rome and Alexandria in 100 A.D. Aretaeus was completely forgotten after his death until around 1554 when his manuscripts, *On the Causes and Indications of Acute and Chronic Diseases* and *On the Treatment of Acute and Chronic Diseases*, were discovered. Both were written in Ionic Greek dialect and contained model descriptions of pleurisy, diphtheria, tetanus, pneumonia, asthma, and epilepsy but also show that he was the first to distinguish between spinal and cerebral paralyses. Aretaeus was the first to name and clearly describe the condition of diabetes, which is Greek for “siphon,” indicative of the diabetic’s intense thirst and excessive emission of fluids, and rendered the earliest clear account of that disease now known (Encyclopedia Britannica Online).

In 1889, two medical researchers in Europe, J. von Mering and O. Minowski, removed the pancreas of a dog to see what would happen. The dog began to urinate a lot, and the researchers noticed there were flies swarming around the pools of urine. When they tested the urine and discovered that it contained sugar, they realized the dog had developed diabetes. Now they knew that diabetes was a disease of the pancreas (Bliss, 1982).

Until this century, the only way doctors had to treat diabetes was through diet. Aretaeus of Cappadocia prescribed a diet of milk, gruel, cereal, and wine. Other doctors throughout history tried a strict meat diet, and still others ordered a diet high in fat. These diets didn’t help, of course. People who developed Type 1 diabetes typically survived only a few months (Bliss, 1982). Type 1 is a form of diabetes that usually develops during childhood or adolescence and is

characterized by a severe deficiency of insulin secretion resulting from atrophy of the Islets of Langerhans and causing hyperglycemia (high blood sugar) (Webster's Dictionary Online).

Then, in 1921, in Toronto, Ontario, Canada, Dr. Frederick G. Banting and a medical student, Charles H. Best, took fluid from animal pancreases, purified it, and injected it into Leonard Thompson, an 11-year-old boy suffering from severe diabetes. Leonard was barely alive and weighed only 75 pounds. After injections of this purified fluid, later to be established as insulin, his blood sugar levels went down, he was able to eat a more normal diet, gained weight, and lived to be an adult (Bliss, 1982). Banting and Best shared the Nobel Peace Prize of Medicine for their discovery of insulin.

Since 1971, scientists have been trying to create an artificial pancreas to try to cure diabetes. With an artificial pancreas, a person with diabetes could control blood sugar levels without injecting insulin (Bliss, 1982).

Definition of Terms

The following definitions apply to the terms used in this research study:

Carbohydrate Counting: An effective way to control insulin regimens by means of giving only enough insulin to cover the grams of carbohydrate ingested.

Diabetes: A disorder of carbohydrate metabolism, usually occurring in genetically predisposed individuals, characterized by inadequate production or utilization of insulin and resulting in excessive amounts of glucose in the blood and urine, excessive thirst, weight loss, and, in some cases, progressive destruction of small blood vessels leading to such complications as infections and gangrene of the limbs or blindness (Webster's Dictionary Online).

Diabetic Ketoacidosis: High blood glucose with the presence of ketones in the urine and bloodstream, often caused by taking too little insulin to treat diabetes or during illness (ADA Online, 2007).

Glycemic: Literally, "causing glucose (sugar) in the blood." Blood glucose is closely related to the amount and type of carbohydrates consumed (Webster's Dictionary Online).

Hemoglobin A1C: A1C, also known as glycated hemoglobin or glycosylated hemoglobin, indicates a patient's blood sugar control over the last 2-3 months. A1C is formed when glucose in the blood binds irreversibly to hemoglobin to form a stable glycated hemoglobin complex. Since the normal life span of red blood cells is 90-120 days, the A1C will only be eliminated when the red cells are replaced (Diabetes Care, 2002).

Hyperglycemia: The presence of an abnormally high concentration of glucose in the blood (Webster's Dictionary Online).

Hypoglycemia: The presence of abnormally low concentrations of glucose in the blood (Webster's Dictionary Online).

Insulin Analogs: These are versions of insulin that have been altered to achieve greater control over blood glucose levels (JDRF, 2007).

Insulin Glargine: Once injected, glargine forms a precipitate which is absorbed very slowly and evenly into the bloodstream lasting for almost 24 hours (JDRF, 2007).

Insulin Pump: An external battery-powered device that injects insulin into the body at a programmed rate to control blood sugars (Webster's Dictionary Online).

Quality of Life: A personal perception of health and well-being and how it affects daily life and activities.

Subcutaneous: Located or placed just beneath the skin (Webster's Dictionary Online).

Type 1 Diabetes: Diabetes of a form that usually develops during childhood or adolescence and is characterized by a severe deficiency of insulin secretion resulting from atrophy of the Islets of Langerhans and causing hyperglycemia and a marked tendency toward ketoacidosis called also *insulin-dependent diabetes*, *insulin-dependent diabetes mellitus*, *juvenile diabetes*, *juvenile-onset diabetes*, *type 1 diabetes mellitus* (Webster's Dictionary Online).

Type 2 Diabetes: Diabetes mellitus of a common form that develops especially in adults and most often in obese individuals, which is characterized by hyperglycemia resulting from impaired insulin utilization coupled with the body's inability to compensate with increased insulin production, called also *adult-onset diabetes*, *late-onset diabetes*, *maturity-onset diabetes*, *non-insulin-dependent diabetes*, *non-insulin-dependent diabetes mellitus*, *type 2 diabetes mellitus* (Webster's Dictionary Online).

Research Statement

The goal of this study was to determine whether continuous subcutaneous insulin infusion is a better way of controlling diabetes than multiple insulin injections. Continuous subcutaneous insulin infusion (CSII) therapy has multiple potential advantages over injection therapy, including an enhanced ability to mimic physiologic insulin release as well as permitting greater flexibility in food intake and physical activity (Pickup, Keen, 2002).

Independent and Dependent Variables

To investigate the research question, a retrospective cohort study design was used with multiple insulin injections being the control group and intensive insulin pump therapy being the experimental group.

Independent Variable

Hemoglobin A1C level on Insulin Pump

Hemoglobin A1C level on Insulin Injections

Diet on Insulin Pump

Diet on Insulin Injections

Exercise on Insulin Pump

Exercise on Insulin Injections

Dependent Variable

< 7% (Recommended) (Diabetes Care, 2002)

< 7% (Recommended) (Diabetes Care, 2002)

3 meals and snacks daily (Recommended) (Rosenstock, et al, 2000)

3 meals and snacks daily (Recommended) (Rosenstock et al, 2000)

3 days /week for 30 minutes (Recommended) (Medline Plus, 2004)

3 days / week for 30 minutes (Recommended) (Medline Plus, 2004)

Opinion of Quality of Life

The outcome measures evaluated are hemoglobin A1C levels, ingestion of consistent meals, frequency of exercise, and the subjects' opinion of their quality of life. The quality of life in uncontrolled diabetics is diminished with complications such as blindness, kidney failure, heart disease, and amputations.

Chapter 2

Review of Literature

Complications with Uncontrolled Diabetes

Living with diabetes in the 21st century is a fortunate situation for most diabetics. An insulin pump helps to greatly reduce the risk of future complications associated with uncontrolled diabetes mellitus. But what exactly are the complications with uncontrolled diabetes?

Hyperglycemia or high blood sugar seems to affect the body's small blood vessels and the nervous system. Over time, high glucose levels change the walls of small blood vessels, causing them to thicken and leak. The vessels may eventually clog, impeding blood flow to vital organs. This clogging or impedance of blood flow may lead to eye disease or retinopathy, nerve damage or neuropathy, kidney disease or nephropathy, and cardiovascular disease (Nathan, 2004).

Scientists don't know what causes retinopathy, but they do know it occurs in two stages. In the first stage, the walls of the small blood vessels become abnormal and weaken. They leak fluid into surrounding tissue, leaving deposits of protein and fat called hard exudates. The vessels also develop micro-aneurysms, tiny bulges or pockets in their walls that tend to leak red blood cells into the retina. As the condition progresses, the abnormal vessels begin to close, robbing the retina of its blood supply. Nerve fibers die off due to poor circulation and lack of oxygen, creating white cottony patches known as soft exudates. These changes may not alter your vision. But if the fluid or blood leakage occurs near the macula, the part of the retina responsible for sharp, central vision, sight will be impaired. After 20 years, nearly all people with type 1 diabetes will have developed retinopathy if blood sugar is not controlled (Nathan, 2004).

Nerve damage, or neuropathy, from diabetes has widespread effects, and again, the blame rests with abnormally high blood sugar levels. When nerve damage occurs, the network of nerves that relays messages to and from different parts of the body slows down, sends the wrong cues, or fails to work. Scientists aren't certain why this happens, but they think the damage may result when glucose attaches to or affects proteins in nerve cells, causing a chemical imbalance inside the nerves or restricting the blood flow to the nerves (Nathan, 2004).

Nerve damage can cause changes in sensory perception, pain, or problems with digestive, bladder, bowel, or sexual function. About 60%-70% of people with diabetes have some signs of neuropathy that may be detectable only with a physical exam or special testing, and a smaller percentage has more severe symptoms. Serious neuropathy, especially when combined with vascular complications, can lead to foot ulcers and the loss of lower limbs (Nathan, 2004).

Diabetes is the leading cause of kidney failure, accounting for about 40% of new cases; most people with diabetes don't develop this life-threatening condition. Kidneys filter toxins and wastes from the bloodstream, flushing them out of the body through urine, while retaining important proteins and other useful substances. This filtering work is done by glomeruli, a delicate network of capillaries. But after prolonged exposure to high blood sugar, capillary membranes thicken, and the glomeruli are damaged and distorted (Nathan, 2004).

Three out of four people with diabetes die from heart disease or stroke. While experts don't fully understand the causal relationship between diabetes and cardiovascular disease, it's clear that diabetes is often accompanied by various heart disease risk factors, such as high blood pressure, high cholesterol, high triglycerides, and obesity. Diabetes is also associated with an increased tendency for forming clots (Nathan, 2004).

Strict control of blood glucose levels is highly important in a diabetic's life to avoid or at least help delay the development of such complications listed previously. It seems to be apparent that diagnosis of any of those complications would severely compromise a diabetic's quality of life. This is why insulin in any way is helpful to stabilize the blood sugar levels.

Different types of diabetes can be controlled by different medications. For instance, Type 2 diabetes can be controlled by diet, or it may take medication to help the body's insulin production work correctly. Later stages of Type 2 diabetes may require insulin for best control. Type 1 diabetes however, requires insulin. It cannot be controlled any other way.

Insulin Analogs and Glargine

In the last decade, one of the most important innovations of blood glucose control was the arrival of insulin analogs. Insulin analogs are versions of insulin that have been altered to achieve greater control over blood glucose levels. Insulin lispro, the first insulin analog, was introduced in August 1996 by Eli Lilly and Company under the brand name Humalog. Humalog is a rapid-acting analog that works much more quickly than regular insulin and lasts only about two hours. This makes it ideal for mealtime insulin injections. Compared to regular insulin, which is supposed to be taken 30 to 45 minutes before meals, Humalog is taken within 15 minutes of eating, which adds flexibility and convenience to meal planning (JDRF, 2007).

Studies show that blood glucose levels two hours after meals are significantly lower in people who use mealtime lispro compared with regular insulin. Another rapid-acting insulin analog is called insulin aspart, manufactured by Novo-Nordisk. Like Humalog, Novolog is also a fast-acting insulin to be used for bolus injection prior to meals. It was approved for marketing in the U.S. by the Food and Drug Administration (FDA) in June 2000 (JDRF, 2007).

In April 2000, the FDA granted marketing approval for insulin glargine or Lantus, which is manufactured by Aventis Pharmaceuticals. Once injected, insulin glargine forms a precipitate, which is absorbed very slowly and evenly into the bloodstream. Since its effects last nearly 24 hours with little variability and no peak action level, insulin glargine is an ideal “basal” or long-acting insulin. A number of studies have compared the use of insulin glargine with that of the most commonly used basal insulin, Neutral Protamine Hagedorn (NPH) (Rosenstock, et al. 2000). Neutral Protamine Hagedorn is a long-acting insulin, which generally is absorbed in the blood over 5-6 hours. Results show, however, that regimens using insulin glargine offer blood glucose control that is at least as good as and sometimes better than that seen with NPH insulin, and it produced fewer episodes of hypoglycemia and less weight gain (JDRF, 2007).

Today, there are many new devices, such as the insulin pump, that can help avoid the rigid rules and loss of freedom that used to be associated with diabetes. The rigid rules of a diabetic’s life used to consist of exact meal timing to make it possible for insulin regimens to be administered at the proper time. Now, the pump seemingly offers a great expansion of freedom to diabetics by allowing exercise, with less risk of hypoglycemia and better glucose control by learning how to carbohydrate count. Carbohydrate counting is an effective way to control insulin regimens by means of giving only enough insulin to cover the grams of carbohydrate ingested. With an insulin pump, you simply add up your carbohydrates ingested, and insert the number into the pump—just like a calculator. The pump then figures out, based on your programmed ratio, how much insulin is needed to cover your carbohydrates. If you are an active person with diabetes, an insulin pump may be a good tool for living a more active and flexible life. The pump is a reliable way to deliver insulin and to give people with diabetes more freedom in their daily activities (Google Image Database).

Insulin Pump

Insulin pumps are small devices, about the size of a pager. One or more microprocessors control the rate and timing of insulin delivery. The first pump delivered both glucagon and insulin. It was developed in 1963. This pump is shown in Figure 1. The next system invented was called The AS2C and came out around 1977. A number of people living with diabetes used this. The next device for insulin delivery was the AutoSyringe AS*6C, which was invented in 1980. It was able to infuse only diluted U-40 insulin at one basal rate. A glucose-controlled insulin infusion system called the BioStar was invented in the 1980s and functioned as an artificial pancreas. The MiniMed was released in the 1990s and is still worn by many people today. The MiniMed is shown in Figure 1. An insulin pump is often worn on the user's belt, slipped inside a pocket, attached to the inside of a dress or undergarment, or worn on an elastic band attached to the user's arm or thigh (Google Image Database).

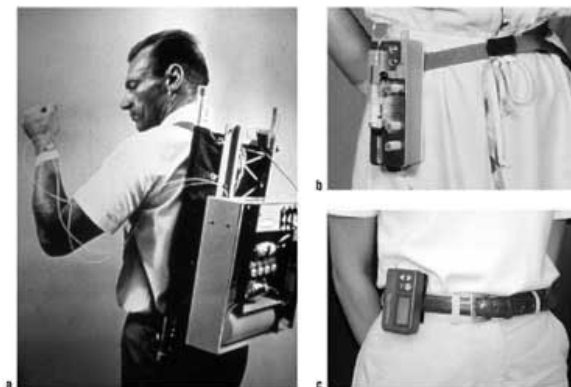


Figure 1. Insulin Pumps (Bode, Tamborlane, Davidson, 2002; Google Image Database)

Insulin pumps use quick acting insulin, such as Humalog, Regular, or Velosulin. Insulin is delivered continuously through a needle inserted in the body, which is connected by a very thin tube to the pump at the other end. The tube and needle are referred to as an “infusion set.” Long acting insulin, such as NPH or UltraLente, is not used in insulin pumps (Google Image Database).

The pump is programmed to deliver a constant background rate of insulin called a basal rate, which may change at various times during the day, to closely match the individual's needs. Typically, the basal rate does not need to be changed often, once the person's blood glucose patterns are known. There may be some variation due to changing sleep / wake schedules or monthly hormonal changes. These changes can be accommodated quite easily with the pump and therefore achieve better blood sugar control than insulin injections (Google Image Database).

A dose of insulin called a "bolus" is programmed to meet the requirements of food intake. This amount of insulin is usually calculated based on the amount of carbohydrates contained in the meal or snack. A bolus can also be programmed to correct high blood glucose readings. The amount of the bolus in these situations is based on how much a given amount of insulin will lower the person's blood glucose level (Google Image Database).

Insulin pumps have made a breakthrough over the last decade. The graph below (Figure 2) suggests that the number of insulin pump users is steadily increasing over the years.

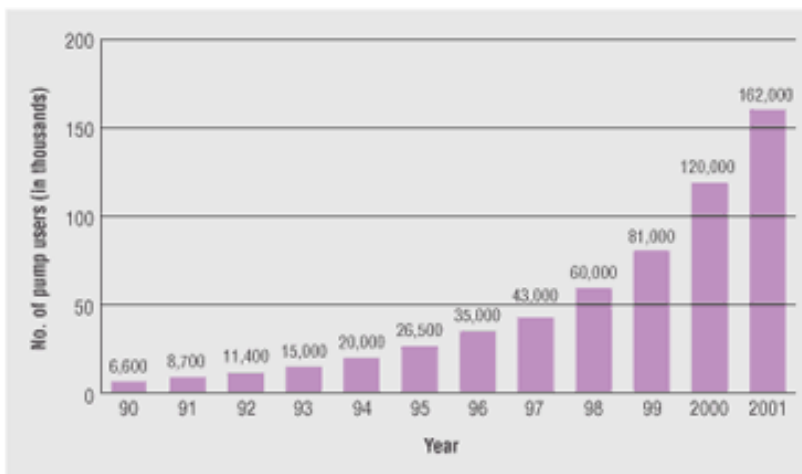


Figure 2. Number of patients using subcutaneous insulin infusion pumps in United States by year (Bode, Tamborlane, Davidson, 2002)

Insulin Pump Advantages

Continuous subcutaneous insulin infusion (CSII) is used in selected type 1 diabetic subjects to achieve strict blood glucose control. A quarter of a century after its introduction, world-wide use of CSII is increasing (Bliss, 1982). Limited evidence shows that this increase is due to the effectiveness of diabetes control by pump therapy compared with modern intensified insulin injection regimens and concern about possible complications. A review of 13 randomized controlled trials showed that in most patients, mean blood glucose concentrations and hemoglobin A1c percentages are either slightly lower or similar on CSII versus multiple insulin injections, with the standardized mean difference being 0.44 (0.20 to 0.63) (Pickup, Mattock, Kerry, 2002). However, hypoglycemia was markedly less frequent than during intensive injection therapy. Ketoacidosis occurred at the same rate. Nocturnal glycemic control is improved with insulin pumps; automatic basal rate changes on the pump help to minimize the pre-breakfast blood glucose increases caused by hormonal elevations in the body known as the “dawn phenomenon” (Nabhan, et al, 2006).

An increase in the blood sugar level between approximately 3:00 a.m. and the time a person wakes is called the “dawn phenomenon.” The liver attempts to release just enough glucose to replace what is being used, and insulin works as the messenger to tell the liver how much is enough. But if there is not enough insulin (as in type 1 diabetes), or if there is adequate insulin but it cannot communicate its messages to the liver (as in type 2 diabetes), the liver starts to release glucose much too fast. The result of this is a rise in blood sugar levels. This is why blood sugar levels can go up between the time a person goes to bed and the time he/she wakes up, even though the individual has not eaten since supper (Pickup, 2006).

Insulin Pump Disadvantages

Ketoacidosis is dangerously high levels of ketones. Ketones are acids that build up in the blood as a result of fat and lean muscle breaking down. In order to move glucose from the bloodstream into cells, insulin is required. If there is not enough insulin present, glucose does not move into the cells and can build up in the bloodstream. When the body senses that cells are not being fed, it will turn to fat stores and lean muscle mass as a source of energy. This happens mainly when a person does not eat enough or there is not enough insulin in the blood stream. Using fat for energy causes the body to make even more glucose. This is in addition to the glucose already circulating in the bloodstream that is unable to enter cells due to the lack of insulin. Blood glucose levels rise higher, more fat is burned as the body starves, and more ketones are produced by the partial oxidation of fat. The kidneys try to cleanse the bloodstream by excreting blood glucose and ketones through the process of urination. This is one of the reason's people with high blood glucose levels have to urinate frequently. But eventually the kidneys become overworked and can no longer keep with the demand. Then, ketones and glucose levels can build up to a level where organ damage, coma, and even death will occur. To make matters even worse, the constant urination can dehydrate a person with diabetes. Hypovolemia concentrates glucose and ketones in the blood making their effects even more damaging (Joslin Diabetes Center Online, 2006). Ketones are thus an important warning sign that a person's diabetes may be out of control or that they are getting sick (ADA, 2006).

Most pump users will agree that the insulin pump's advantages far outweigh the disadvantages. However, it is important to recognize the disadvantages before initiating insulin pump therapy. Use of the insulin pump may cause weight gain; it can be expensive without help from insurance providers; it can be bothersome since the pump is attached to the body most of the time; and initiation of the pump can require a hospital stay or a full day at an outpatient

center to be trained; and if the pump's catheter comes out from the body site (abdomen, upper buttocks, upper thigh, or the triceps area of the arm) unbeknownst to the patient, diabetic ketoacidosis can occur from lack of insulin infusion (ADA, 2006). Catheter sites generally used are shown in Figure 3.

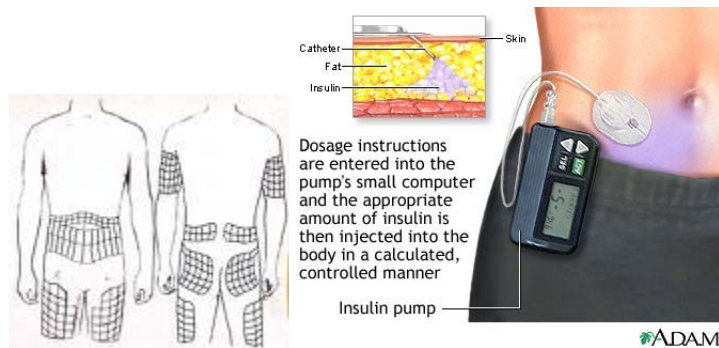


Figure 3. Catheter Example (Diabetes Forecast, 2006; Google Image Database)

Transitioning to the Insulin Pump

Some studies suggest an increased risk of diabetic ketoacidosis (DKA) on CSII compared to injections whereas others show a reduction in DKA rates. Similarly, glycemic control has been reported to improve or remain unchanged. Most studies, however, concur that episodes of severe hypoglycemia appear to decrease while on CSII (Pickup, Keen, 2002).

A study completed by Riley Hospital in Indianapolis, Indiana, documented the initial transition onto the insulin pump in children. The following variables were measured: control of diabetes, number of injections daily prior to pump use, type of insulin used and history of compliance with doctor recommendations regarding blood glucose control, and, last, diabetes camp attendance (Pickup, Keen, 2002).

Before initiation of pump therapy, all families and patients attended a half-day education session, during which insulin types, insulin adjustment, and carbohydrate counting were reviewed. Families that had not previously used carbohydrate/insulin ratios or corrective doses

began using these techniques after the education sessions. At the time of pump therapy initiation, all patients held their morning dose of long acting insulin, began using their pump by late morning, and remained through the afternoon for a second education session with a nurse educator during which patients and families were taught the mechanics of pump use. For the first 10 days, families were asked to check their child's blood sugar at least eight times per day, with tests before meals, before snacks, at midnight, and at 3 a.m. Families were also asked to change infusion sets every 3 days (Pickup, Keen, 2002). Infusion sets are the site at which the insulin pump is placed. It should be changed every 3 days to avoid infection and irritation of the area of skin at which it is placed. Shown below is a picture of a "site." This is a bandage-like patch that contains the catheter as discussed above. This patch is shown below in Figure 4. The catheter is the way the insulin moves from the insulin pump to just inside the body's subcutaneous fat layer before being up taken by the blood stream to reach the cells for use. The site is placed on one of these parts of the body shown in Figure 4. At each 3-day interval, the site should move to a new area to avoid creation of scar tissue.



Figure 4. Infusion Sites (Medtronic Online, 2006; Diabetes Forecast, 2006)

This study concluded that "Average HbA1c prior to pump start was $8.7 \pm 0.9\%$. By 6 months post-CSII start, average HbA1c dropped to $8.1 \pm 0.9\%$ and then rose to $8.2 \pm 0.8\%$ at 12 months. At the time of the last available follow-up after a mean duration of pump therapy of 2.4 ± 0.8 years, HbA1c was $8.3 \pm 0.6\%$. As of May 14, 2006, roughly two and half years after the study initiated, 46 patients (18 boys and 28 girls) were in better control than the initial average,

with an average HbA1c of $7.8 \pm 0.4\%$ (range, 7.0–9.0%) and 47 (17 boys and 30 girls) were in poor control with an average HbA1c of $8.7 \pm 0.6\%$ (range, 8.0–11.0%)” (Pickup, Keen, 2002).

Insulin pump therapy offers a constant rate of insulin that is most closely mimicked by an insulin glargine such as Lantus. Lantus offers a “basal-like” background rate of insulin going into the body for 24 hours. A basal rate is a constant rate of insulin being administered to the body in a small dose that is delivered continuously each hour. The basal rate usually makes up 40 to 50 % of a typical day’s insulin requirements. Most pump users have more than a single basal rate during the day. The basal rate can be adjusted up or down, usually in 0.1 unit increments, during periods of decreased (i.e. exercise) or increased (i.e. sick days, stress) insulin requirements. The basal rate should keep the blood glucose within the desired range (70-120mg/dL) between meals and overnight. If the basal rate is set correctly, the pump user should be able to skip or delay meals without resulting high or low blood glucose (Medtronic Online, 2006). Although it was not documented, the improvement in glycemic control with younger patients may pertain to more parental supervision and support while on CSII therapy (Pickup, Keen, 2002).

Young children may benefit from insulin pump use the most due to the fact that controlled diabetes from an earlier age decreases future complications that are associated with uncontrolled glucose levels over many years of life. The DeVos Children’s Hospital in Grand Rapids, Michigan, evaluated the safety and efficacy of CSII in children aged 2-7 years in a retrospective study (Berhe, et al, 2005). Data were collected from chart review over 2 years. Patients were on NPH + Humalog at least one year prior to CSII initiation. The results of the study showed that the total insulin requirement was higher during twice-a-day injections than to CSII. Also, the average fasting blood sugar was lower in pump therapy, severe hypoglycemic

episodes were higher before pump therapy, and Hemoglobin A1c levels were lower after CSII initiation (Berhe, et, al, 2005).

The study concluded that CSII therapy is safe and effective in young children with type 1 diabetes and is a superior alternative to twice daily insulin regimens (Berhe, et al, 2005). Insulin pump therapy has been successful in adolescents while its use has been limited in young children. Adults are able to be successful on the pump. However, limited studies have been completed to show the advantages of pump use.

Adults and Insulin Pump Therapy

At the Atlanta Diabetes Associates, adults and adolescents on the insulin pump have been investigated. This clinic used its patients for this study. The following were analyzed for the study: the patients' blood glucose log books, insulin doses, if they counted carbohydrates versus an undefined diet, and whether they used insulin lispro or regular insulin. Among 413 adult patients with type 1 diabetes who used a pump, the average HbA1c value decreased from 8.3% to 7.5% over a mean of 3 years (normal value, <6.1%). Among 50 adolescent patients who used CSII for a mean of 3.5+3.9 years, a significant decline in the average HbA1c level was observed, from 9.6% before initiation of pump therapy to 8.3% after initiation of pump therapy (Bode, Tamborlane, Davidson, 2002).

Analysis of patients during routine follow-up visits identified several factors key to successful treatment with insulin pumps. The most important was frequency of blood glucose monitoring. It was found that patients who monitored blood glucose levels three or more times a day had a lower average HbA1c level than patients who monitored levels once or twice daily (7.2% versus 8%). Of the 106 patients who stated that they monitored blood glucose levels five or more times a day, 66 (62%) had an average HbA1c level of less than 7%. Each additional

blood glucose measurement obtained daily corresponded to a 0.2% reduction in HbA1c (Bode, Tamborlane, Davidson, 2002).

Patients who use pump therapy would seem to be at greater risk for the rapid development of diabetic ketoacidosis than those who use insulin injections. This risk comes because some insulin pump users forget or completely eliminate testing blood sugars, causing frequent fluctuations in the blood sugar. However, it was observed in this study that there was a reduction in ketoacidosis rates in both adolescent and adult groups. This reduction was achieved through patient education on how to treat high blood glucose levels. Patients were instructed to give themselves a manual subcutaneous insulin injection if ketone bodies were present in the urine or if blood glucose levels were greater than 250 mg/dL for two consecutive readings. They were then also told to change their infusion set to be sure that there were no occlusions in the tubing or catheter (Bode, Tamborlane, Davidson, 2002).

Summary

Insulin pumps have made a breakthrough in the past decade. The 21st century continues to show promise in eliminating harmful long term complications with diabetes. Most studies have been based on child and adolescent insulin pump therapy. There have been only a limited number of studies concluded in adults. This study therefore compared adult intensive insulin pump therapy vs. multiple injection therapy use and its effects on the quality of life and overall improvement of glucose control of type 1 insulin dependent adults.

Rationale for the Study

Insulin is the only method of controlling Type 1 diabetes. Insulin can be delivered either by multiple injection therapy or by insulin pump. There is not adequate data available comparing intensive insulin pump therapy and multiple insulin injection therapy to treat diabetes. The

pump seemingly helps tighten the control of blood glucose, thus decreasing the risk of complications with diabetes. This research was therefore undertaken to investigate which tool for diabetes control, intensive insulin pump therapy or multiple insulin injections, has the greatest effect on the quality of life of a diabetic by means of lowering hemoglobin A1C levels (3 month average of blood sugar levels), increasing frequency of exercise, and maintaining consistent meal patterns.

Chapter 3

Research Methodology

Overview of Study

The primary purpose of this research study was to analyze the effects of intensive insulin pump therapy vs. multiple insulin injection therapy on the quality of life in adult type 1 insulin dependent diabetics by means of lowering hemoglobin A1C levels, increasing exercise, and ingesting consistent meals daily. Insulin dependent type 2 diabetics were eliminated from the study due to the fact that most also rely on oral diabetic agents to control their glycemic levels.

The groups consisted of 30-45 year old adult diabetics in an endocrinology and diabetes center in a suburban area of Port Huron, Michigan. The sample was made up of 20 subjects (n=20); the multiple injection therapy group (control) contained seven (7) patients, and the intensive insulin pump therapy group (experimental) consisted of thirteen (13) patients.

First, the endocrinologist obtained consent from the patient regarding participation in the study (Appendix A). Once consent was given by the patient, the researcher contacted the patient by phone and administered a telephone survey (Appendix B or C). At the completion of the survey, the patient's chart was studied to examine hemoglobin A1C. Each subject was assigned a number to provide anonymity and the information was recorded. Participants who chose to see the results of the study were notified by mail.

Hypothesis

The following hypothesis was tested in this research: There is a significant difference in adult diabetics' overall health and quality of life when multiple insulin injections are used compared to intensive insulin pump therapy.

Description of Sample

The sample used in this research study was a randomized group that consisted of a total of 20 subjects (n=20). The sample was derived from a suburban endocrinology and diabetes center. This office is located in an established community in Port Huron, Michigan. The subjects ranged in age from 30-45 years. Seven (7) of the subjects were currently using multiple insulin injection therapy (control), and thirteen (13) of the subjects were currently on intensive insulin pump therapy (experimental).

Research Study Design

A retrospective cohort study design was used. A pilot study was conducted initially with six subjects (n=6) to validate the survey tools being used in the study. Once the pilot study was completed with no revisions to the surveys, consent forms (Appendix A) were mailed to the study participants. Once signed, participants returned the informed consent forms to endocrinologist Sushma Reddy, MD. The researcher then telephoned subjects and administered a short survey regarding exercise, meal consistency, and quality of life. Daily meal consistency, exercise, and quality of life opinions were used to compare lifestyles of those using the insulin pump to subjects using insulin injections. Once the surveys were completed, the researcher obtained information from patients' charts regarding hemoglobin A1C levels.

Following the completion of the surveys and chart observations, the following comparisons were made:

- Analysis of subjects' charted HbA1C were evaluated using a 2-mean hypothesis test to determine if pump users' HbA1C was less than that of multiple injection therapy subjects.
- Analysis of subjects' self-reported exercise habits using a 2-sample hypothesis test, to determine if pump users' exercise was greater than the exercise of multiple injection therapy subjects.

- Analysis of subjects' self-reported dietary intake, using a 2-proportion hypothesis test, to determine if pump users intake is closer to the recommended 3 meals and 3 snacks a day than the multiple injection therapy subjects.
- Analysis of subjects' self-reported quality of life, using a 2-proportion hypothesis test, to determine if pump users feel they are in better health regarding their diabetes than the subjects using multiple injection therapy.

This study was approved by Eastern Michigan University's Human Subjects Review Committee prior to study inception (Appendix D). Patients were kept completely anonymous and their responses were confidential.

Chapter 4

Results and Conclusions

Results

After the analysis, patients' hemoglobin A1C levels, exercise patterns, meal patterns frequency, and quality of life revealed the following: Hemoglobin A1C concentrations were obtained from charts of patients who received multiple insulin injections or insulin pump therapy once consent was received. The data (Table 1) were analyzed using a 2-sample hypothesis test to determine if insulin pump users' hemoglobin A1C concentrations were lower than those of insulin injection users. The researcher accepted the null hypothesis and rejected the alternative that at the $p=.05$ significance level, there was no statistical evidence to support the claim that pump users had lower hemoglobin A1C than those using insulin injections. Individual values for hemoglobin A1C for injection users and Pump therapy users (%) are depicted in Table 1. Average hemoglobin A1C's are illustrated in Figure 5. Multiple injection therapy averaged a hemoglobin A1C level of 6.8% compared to intensive insulin pump therapy, which averaged 7.9%.

Table 1. Hemoglobin A1C Results

Hemoglobin A1C values in patients who used insulin injections (n=7) versus patients who used insulin pump therapy (n=13). There is no statistical evidence to support pump users HbA1C is less than that of injection users.

Insulin Injection Results	Insulin Pump Therapy Results
6.5	7.9
5.5	7.8
6.7	6.9
8.0	8.1
8.2	7.9
6.6	8.0
6.6	8.0
	8.5
	7.6
	8.2
	9.2
	6.8
	7.8

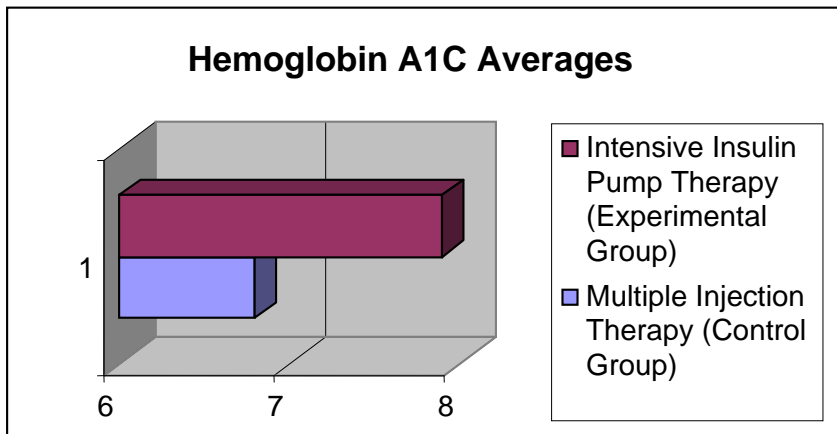


Figure 5. Hemoglobin A1C Averages

During the survey, participants were asked how many days a week they exercised and what types of activities they were involved in. The data (Table 2) were analyzed using a 2-sample

hypothesis test to determine if pump users exercised more days in a week than multiple injection therapy subjects. The null hypothesis was rejected and the alternative hypothesis was accepted at the $p=.05$ significance level. The results revealed that insulin pump users do exercise more than insulin injection users. Results are depicted in Table 2. Multiple insulin injection therapy subjects' weekly average exercise was 0.42 days, compared to intensive insulin pump therapy subjects who reported exercising for 2.1 days on an average every week.

Table 2. Exercise Results

Exercise days per week reported by insulin injection users (n=7) versus insulin pump users (n=13). Results revealed that insulin pump users exercise more than insulin injection users.

Insulin Injection Results	Insulin Pump Therapy Results
0	3
0	0
0	3
0	0
0	7
1	0
2	0
	0
	0
	1
	5
	2
	7

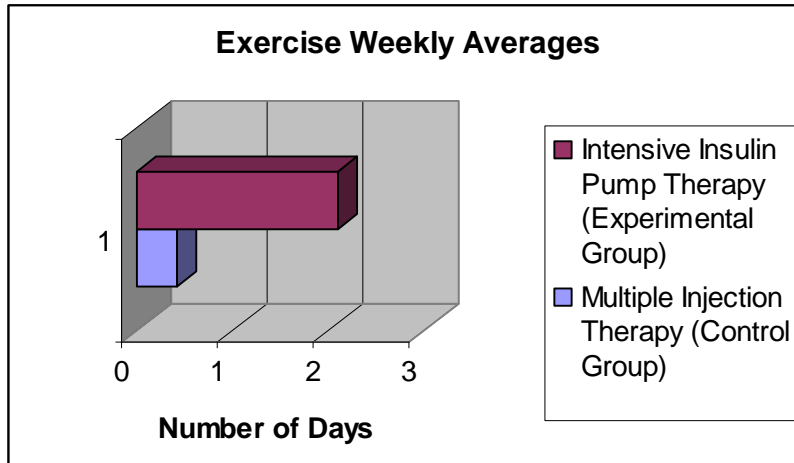


Figure 6. Exercise Weekly Averages

Consuming regular meals is vital for diabetic patients. The next variable tested whether diabetic patients on the pump consumed more frequent meals compared with those receiving multiple insulin injections. A 2-proportion hypothesis test was used to compare whether more pump users consume 3 meals and 3 snacks a day compared to insulin injection users. Data (Table 3) analysis resulted in the rejection of the null hypothesis and acceptance of the alternative at the $p=.05$ significance level concluding that pump users are more likely to ingest 3 meals and 3 snacks a day than insulin injections users. Results are represented in Figure 7. The blue portion of the chart represents the percentage of those who consistently consumed 3 meals/3 snacks a day, and the red portion shows the percentage of those who did not. Fifty-three point nine percent of subjects on pump therapy consumed at least 3 meals/3 snacks every day, whereas only 42.7% of injection users responded that they did so.

Table 3. Meal Consistency Results

Consumption of 3 meals / 3 snacks per day reported by insulin injection users (n=7) versus insulin pump users (n=13). Data suggested that Insulin pump users are more likely than insulin injection users to eat 3 meals / 3 snacks per day.

Insulin Injection Results	Insulin Pump Therapy Results
No	Yes
No	Yes
Yes	No
Yes	No
No	No
No	No
Yes	No
	Yes
	Yes
	No
	Yes
	Yes
	Yes

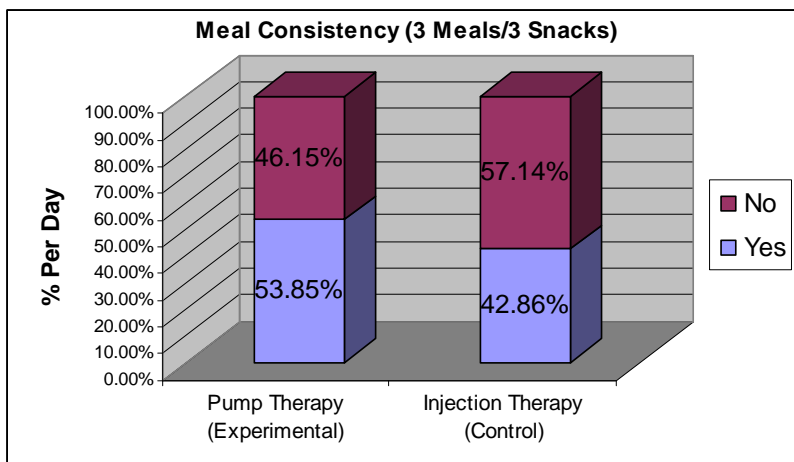


Figure 7. Meal Consistency

Last, overall quality of life of participants who used the pump versus those who received insulin injections was subjectively assessed and compared. Each subject was asked a question

pertaining to his/her opinion of his/her overall quality of life related to his/her diabetes. The subjects were offered only two answers: yes for good health or no for poor health. Analysis of the data (Table 4), using a 2-proportion hypothesis test, at the $p=.05$ significance level, rejected the null hypothesis and accepted the alternative that pump users feel that they are in better health than insulin injection users. Results are illustrated in Figure 8 below. The blue portion of the chart represents the percentage of subjects who felt they had a high quality of life, and the red portion represents the percentage of subjects who felt they had a lower quality of life. Ninety-two percent of pump users thought that they were in good health compared to 71 % of participants who received multiple insulin injections.

Table 4. Quality of Life Results

Quality of Life opinions reported by insulin injection users (n=7) versus insulin pump users (n=13). It was determined that Insulin pump users feel they are in better health than insulin injection users.

Insulin Injection Results	Insulin Pump Therapy Results
Yes	Yes
No	Yes
No	Yes
Yes	Yes
Yes	Yes
Yes	Yes
Yes	Yes
	No
	Yes
	Yes
	Yes
	Yes
	Yes

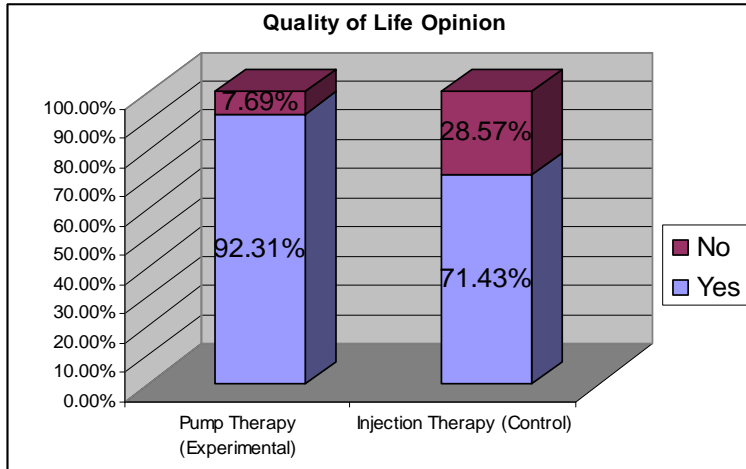


Figure 8. Quality of Life Opinion

Chapter 5

Discussion

Discussion

The four parameters evaluated in this study in type 1 diabetic patients who received insulin either via multiple injections or via a pump were hemoglobin A1 concentrations to reflect long term glycemic control, frequency of weekly exercise, consumption of 3 meals/snacks daily and self-reported opinions about quality of life. Compared to patients receiving multiple injections, patients using the insulin pump did not have lower hemoglobin A1C concentrations, suggesting that pump users did not necessarily have an improved regulation of their blood sugar. However, pump users reported that they exercised better, consumed more frequent meals, and generally felt that they had a better quality of life than patients receiving insulin injections.

Multiple injection therapy patients' hemoglobin A1C levels were significantly lower than insulin pump users. An A1C level gives patients an assessment of average blood glucose levels for the past 2-3 months. When blood sugar is unregulated, the excess glucose enters the red blood cell and glyicates with hemoglobin. The higher the levels of excess glucose in the blood, more hemoglobin gets glycated and the higher the levels of HbA1C. Since the lifespan of a red blood cell is about 120 days, HbA1c levels in the blood reflect blood sugar concentrations for the last 3-4 months. The American Diabetes Association recommends an A1C level of < 7 % in diabetic patients following treatment, referenced to a non-diabetic range of 4.0–6.0%. Earlier studies described in Chapter 2 of this thesis suggested that patients using the pump did improve their glycemic control. It is important to recognize that limited numbers of patients in this study may have impacted the results. Most physicians these days encourage patients on insulin to

switch to using a pump. It was thus difficult to locate patients who still utilized multiple insulin injections. Thus with the control sample size being limited for multiple injection therapy, it is possible that further studies may reveal that multiple injection or pump therapy are equally effective for controlling blood sugar. Nevertheless, only two of thirteen patients evaluated using the pump had HbA1C values that were below 7.0% whereas five of the seven patients tested on the pump had HbA1C values that were below 7.0%. It is pertinent to note here that all these patients were screened at the same clinic. The likelihood of high hemoglobin A1C levels in pump users may be due to erratic scheduling, diet inconsistencies (time frame changes), and perception of more flexibility to eat high carbohydrate foods without the problem of covering with insulin injections. Another possibility behind insulin injection users HbA1C being lower than pump users could be the fact that injection users may exhibit more hypoglycemic reactions than insulin pump users. Since pump users described their quality of life as being better, it is also possible that they get lulled into believing that they need not keep an eye on their diets regularly. And although they reported that they consumed regular meals, this study did not compare or take into account the quality or nutritive content of the diet consumed. Thus pump users could be consuming more carbohydrates and/or simple sugars, resulting in their inferior values for HbA1C. Our results thus indicate that although there may be improvement in regulating blood sugar in pump users, patients using multiple injections fared better and had a much superior glycemic control.

It was found that insulin pump subjects were more likely to exercise than multiple injection therapy users. Reasons given by participants varied; however, most often scheduling conflicts were the reason behind lack of exercise. Interestingly, in either group hypoglycemia was not of concern as a barrier to exercise.

Participants were questioned about their daily meal planning. It was found that insulin pump users were more likely to consume 3 meals and 3 snacks a day (than multiple injection therapy subjects.) Patients were not questioned as to why their meals were not consistent. However, injection participants were asked if they count carbohydrates, and three out of four participants answered yes. Likewise, the insulin pump participants were asked if they carbohydrate counted prior to the insulin pump, and seven out of the thirteen participants answered no. Thus as stated before, pump users could perceive that being on the pump rendered them the flexibility to not watch their diets as keenly as non-pump users.

The last feature evaluated was the patients' opinion of their quality of life. Intensive insulin pump subjects' perception of their lives were superior to those on multiple injection therapies. Pump users' reasons for feeling they have a better quality of life was better control (according to them) over their blood sugar readings, freedom—not having to worry about injecting before meals—and a more “normal” life. It should also be stated that all thirteen pump users questioned regarding whether they would recommend the insulin pump to injection users stated yes.

Thus although diabetic patients exercised more frequently, regulated their meal intake, and professed that they were in better health while using the pump, in reality their glycemic control was not superior to patients who used multiple insulin injections.

Limitations

In this study there were two limitations that were noted. The first limitation was that the age group was too limited for insulin injection therapy. By the ages 30-45 years, it was found that most type 1 insulin dependent diabetics prefer pump therapy for easier control.

The second limitation was sample size. The goal was to recruit 40 subjects: 20 multiple injection therapy and 20 insulin pump users. Once consent forms were received it was discovered that limited participants were available at the particular endocrinology and diabetes center. A more expansive sample may have shown a better comparison of the two groups studied.

Suggestions for Change

If this research were to be replicated, it would be recommended that the age group be expanded by five years on both ends, changing it from 30-45 to 25-50 years. This would result in an increase of the sample size.

Another aspect that could increase sample size would be to include type 2 insulin dependent diabetics and factor in the use of oral agents. Type 2 diabetics on insulin weren't able to be used because they also were receiving oral agents along with insulin for best control, and the results may have been skewed had these patients been used in the data.

The next change would be the time frame. If more time were allotted to the project, surveys could be completed in person. This survey was completed entirely over the telephone. The participants spoke with the researcher for roughly 10-15 minutes. However, it is thought that with an in-person survey, participants may be more likely to share more personal information than with a researcher over the telephone.

Last, incorporating additional endocrinologists throughout the mid-Michigan area and possibly over the country into the study, as opposed to one suburban location, would help to increase the sample size. This may also help contribute to different ethnicities and populations.

Conclusions and Significance

The overall conclusion of this study was that the hypothesis that “there is a significant improvement in adult diabetics’ overall health and quality of life when using intensive pump

therapy compared to multiple insulin injections” was disproved. Although three out of the four parameters studied – frequency of exercise, consumption of regular meals/snacks, and overall self-reported quality of life - were better in pump users, hemoglobin A1C, the only measurable outcome that correctly reflects glycemic control, was not enhanced in patients on the pump compared to patients receiving multiple insulin injections. Thus, although patients on the insulin pump therapy perceived that their health was improved, this study concludes that intensive pump therapy may not be a better treatment than multiple insulin injections.

Health care providers, particularly physicians and dietitians who treat diabetic patients, should not become complacent with diabetic patients receiving insulin pump therapy. They should recognize this problem with glycemic control in insulin pump users and counsel them to watch their diets and frequently monitor their blood sugar. This study thus has important implications in diabetes care and management.

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Appendix A

Insulin Pump Study Consent Form

The purpose of this study is to determine whether continuous subcutaneous insulin infusion (insulin pump) is a better way of controlling diabetes than insulin injections. This will show if it is significant in helping to improve the quality of life in diabetics by means of improving hemoglobin A1c levels, diet and exercise and possibly decrease risk of long term complications associated with diabetes.

The research undertaken in this study will investigate the effects of intensive insulin pump therapy vs. multiple injection therapy on the quality of life in adult insulin dependent diabetics by means of lowering hemoglobin A1c levels, increasing exercise due to decreased fear of hyper or hypo-glycemia and healthier eating. The study will focus on five variables:

1. Hemoglobin A1c level (below 7%).
2. Weight changes (Average over the past year).
3. Exercise (3 times a week for 30 minutes or more).
4. Diet (Eating 3 meals and 3 snacks daily).
5. Quality of Life (Subject opinion).

You can help in this project by allowing research to be concluded through use of your medical charts and also complete a 10-15 minute telephone survey with the investigator. Participation in this project is strictly voluntary. You are free to withdraw your participation at any time.

When the telephone survey is complete, your name will not be attached to the transcript. A number will be assigned to your particular case, protecting your identity. This informed consent form, with your name, will not be matched with the data, and your participation will be kept confidential.

Any questions or concerns regarding the study, survey or procedures of this research are to be directed to Dr. Stephen Sonstein, chair Human Subjects review committee of the College of Health and Human Services at Eastern Michigan University, Ypsilanti, Mi-48197. He can be reached at (734) 487-1238 or at Stephen.sonstein@emich.edu or Dr. Anahita Mistry at phone number (734)-487-5079 or through email amistry@emich.edu.

Appendix A

Insulin Pump Study Consent Form

It is my right to withdraw at anytime from completion of the study without penalty. I have read all of the above information regarding this study. The procedures and requirements have been explained to me and I understand them. I freely and voluntarily consent to be a participant. For my records, I have been provided with a copy of this consent form.

I understand that my personal medical charts will be used but also understand that the information that I give will be held in the strictest confidence and that my responses will be kept separate from my identifying information.

Name

Date

I elect to have the results of this study mailed to me through standard mail.

Yes

No

If yes, please provide your mailing information below:

Street Address

City, State, Zip Code

Any questions regarding the study results, survey or procedures of this research are to be directed to Dr. Anahita Mistry at phone number (734)-487-5079 or through email amistry@emich.edu.

Appendix B

Insulin Pump Study Telephone Survey

Please answer the following questions about you and your insulin pump history.
All information will be kept confidential.

Exercise

Please answer the following questions:

How many days a week do you exercise 30 minutes or more? 1 2 3 4 5 6 7

What types of activities are you involved in?

If your activity improved after getting on the insulin pump, please explain why you think this may be (i.e. less fear of hypoglycemia (low blood sugar)):

Diet

Please answer the following to the best of your knowledge.

Did you use carbohydrate counting prior to insulin pump use? Yes No

Do you think carbohydrate counting after insulin pump initiation
has improved your diet? Yes No

Do you find any difficulties in carbohydrate counting? Please explain:

Diet Diary

Please record everything you ate for 1 week day and 1 weekend day at every meal and snack hour to the best of your ability.

Weekday

Breakfast:

Snack:

Lunch:

Snack:

Dinner:

Snack:

Weekend day

Breakfast:

Snack:

Lunch:

Snack:

Dinner:

Snack:

Quality of Life

Please answer the following:

Overall, in your opinion, do you think your health has improved while using the pump compared to insulin injection regimens?

Yes No No change

Would you encourage others to use an insulin pump if recommended by their physician?

Yes No No opinion

Please explain why you feel the pump has or has not increased the quality of your life and health:

Appendix C

Insulin Injection Study Telephone Survey

Please answer the following questions about you and your insulin injection history.
All information will be kept confidential.

Exercise

Please answer the following questions:

How many days a week do you exercise 30 minutes or more? 1 2 3 4 5 6 7
What types of activities are you involved in?

Diet

Please answer the following to the best of your knowledge.

Do you use carbohydrate counting? YesNo

If you answered No, to the above question, do you think carbohydrate counting could improve your diet?

YesNo

If you use carbohydrate counting, do you find any difficulties in carbohydrate counting? Please explain:

Diet Diary

Please record everything you ate for 1 week day and 1 weekend day at every meal and snack hour to the best of your ability.

Weekday

Breakfast:

Snack:

Lunch:

Snack:

Dinner:

Snack:

Weekend day

Breakfast:

Snack:

Lunch:

Snack:

Dinner:

Snack:

Quality of Life

Please answer the following:

Overall, in your opinion, do you think you are in good health regarding your diabetes?

Yes No No change

Would you consider the use of an intensive insulin pump therapy if recommended by your physician?

Yes No No opinion

Please explain why you feel the pump may or may not increased the quality of your life and health:

Appendix D

Approval from Human Subjects Committee Eastern Michigan University



EASTERN MICHIGAN UNIVERSITY

January 16, 2007

Katie Reynolds
c/o Anahita Mistry, PhD
School of Health Sciences
Eastern Michigan University
Ypsilanti, MI 48197

Dear Ms. Reynolds,

The CHHS Human Subject Review Committee has reviewed your request entitled "Quality Of Life Of Diabetic Subjects Using The Pump To Deliver Insulin Compared With Those Taking Insulin Injections" submitted on January 8, 2007. The Committee unanimously agreed that it meets the Minimal Risk standards and that the study can be initiated.

The Committee may request further approval if secondary analysis of the data is conducted.

Sincerely,

Stephen A. Sonstein, PhD
Chair, CHHS Human Subjects Review Committee

Appendix E

List of Abbreviations

HbA1C: Hemoglobin A1C

ADA: American Diabetes Association

JDRF: Juvenile Diabetes Research Foundation

NPH: Neutral Protamine Hagedorn

CSII: Continuous Subcutaneous Insulin Infusion

FDA: Food and Drug Administration

DKA: Diabetic Ketoacidosis