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Continuous Subcutaneous Insulin Infusion for Type 2 Diabetes Mellitus

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PERMISSION

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Abstract

Continuous subcutaneous insulin infusion (CSII), or insulin pump therapy, is an important and effective treatment option for patients with diabetes. To date, CSII is largely utilized in the type 1 diabetic population. As demonstrated in the following case report, initiation of CSII for a type 1 brittle diabetic was effective in gaining glycemic control. Of the 29.1 million people diagnosed with diabetes, 90-95% have type 2 diabetes. As the patient with type 2 diabetes becomes more insulin resistant, multiple daily injections (MDI) of insulin are needed to attain glycemic control, but oftentimes these efforts fail. A literature review was performed to determine whether CSII versus MDI in the uncontrolled type 2 diabetic patient would improve patient outcomes based on the factors of effectiveness, safety, and cost-efficiency. Evidence suggests that while CSII therapy is effective at lowering hemoglobin A1c, and is safe in regards to both reducing hypoglycemic events and in operating the insulin pump, it may not be cost efficient due to limited insurance coverage for this population. Being that CSII effectively attains glycemic goals, risks for complications from poor glycemic control are reduced. More research and cost analysis is needed to determine if the expense of CSII outweighs the medical costs of complications related to uncontrolled diabetes.

Background

In the United States, diabetes mellitus affects an estimated 29.1 million people. It was the 7th leading cause of death in 2010, and in 2012, accrued $245 billion in direct and indirect medical costs (Centers for Disease Control and Prevention, 2015). A diagnosis of diabetes can be devastating. Alongside financial burdens, *Healthy People 2020* discusses that diabetes also "lowers life expectancy by up to 15 years, increases the risk of heart disease by two to four times, and is the leading cause of kidney failure, lower limb amputations, and adult-onset blindness" (Office of Disease Prevention and Health Promotion, 2014). Fortunately, there are many tools available to manage diabetes and proper management can significantly reduce the risks of complications from diabetes. This is illustrated in the following case.

A 67-year old male presents for a preoperative exam for a right total knee replacement. His past medical history includes type 1 diabetes mellitus, hypertension, and hyperlipidemia. He was diagnosed with type 1 diabetes in his early adulthood and has considered himself a brittle diabetic for most of his life. Three years ago, he transitioned his diabetic management from multiple daily injections of insulin (MDI) to continuous subcutaneous insulin infusion (CSII), most commonly referred to as insulin pump therapy. After over 40 years of struggle in managing his disease, this transition was what this patient needed to take adequate control of his diabetes.

Research suggests that using insulin pump therapy assists patients affected by type 1 diabetes to meet their goals and reduce long-term complications. Due to its proven benefit, Medicare, as well as private insurance carriers, help defer the cost of insulin pump therapy for type 1 diabetes. Strikingly, of those diagnosed with diabetes, type 1 accounts for only 5%, while

type 2 encompasses 90-95% of total diagnosed cases (Centers for Disease Control and Prevention, 2015). While limited studies have been performed regarding insulin pump therapy for the patient with type 2 diabetes, is there enough evidence to suggest that the patient with uncontrolled type 2 diabetes would have improved outcomes with insulin pump therapy versus multiple daily insulin injections? With this literature review, an attempt will be made to answer this question as well as whether insulin pump therapy is safe, effective, and cost-efficient for this population.

Case Report

The patient who presented for his preoperative examination was considered a brittle diabetic and had been diagnosed with type 1 diabetes in his early twenties. The National Institute of Diabetes and Digestive and Kidney Diseases (2014) describes type 1 diabetes as when "your body no longer makes insulin or enough insulin because the body's immune system has attacked and destroyed the pancreatic cells that make insulin". Type 2 diabetes develops differently, beginning with the body's resistance to insulin and advancing to the point where the pancreas is unable to make enough insulin to combat blood glucose levels. As type 2 diabetes advances, the body starts to depend on insulin injections for blood glucose control (National Institute of Diabetes and Digestive and Kidney Diseases, 2014). Due to the disease, this patient is dependent upon insulin injections and strict monitoring of dietary choices to regulate his blood glucose. For 40 years of this patient's life, he was giving himself shots of insulin multiple times per day and he was still uncontrolled. Just three years ago, he was placed on insulin pump therapy and has since attained glycemic control.

Glycemic control is determined by hemoglobin A1c monitoring, which correlates to an average reading of blood glucose levels over a two- to three-month period. The American Diabetes Association (2016) defines a normal hemoglobin A1c as <5.7%, pre-diabetes as 5.7% to 6.4%, and diabetes as any number greater than 6.5%. After diagnosis of diabetes, the goal is to reduce hemoglobin A1c to near-normal levels, but health status and patient individualization is taken into account. According to the guideline published by the National Guideline Clearinghouse, *Diagnosis and Management of Type 2 Diabetes Mellitus in Adults*, hemoglobin A1c should be individualized for each patient in a range from <7% to <8% (Agency for Healthcare Research and Quality, 2014). Achieving near normal levels, lowers the risk of microvascular complications such as retinopathy, nephropathy, and amputations and may also significantly reduce macrovascular complications such as heart attack and stroke (Agency for Healthcare Research and Quality, 2014). This patient has annual eye exams with no evidence of retinopathy, his renal function is adequate based on his BUN of 9mg/dL and creatinine of 0.8 mg/dL. He has no evidence of peripheral neuropathy, peripheral vascular disease, and has not had a heart attack or stroke.

This patient had his hemoglobin A1c checked as part of the preoperative examination and his result was 7.0%. Alongside hemoglobin A1c levels, a patient should also be monitoring finger stick blood glucose readings at home. Multiple readings throughout the day will guide the patient in dosing insulin injections and in preventing episodes of hypo- or hyperglycemia. When he checks his blood glucose at home, his numbers range from 140-180 mg/dL. He also reports that since starting pump therapy, his incidences of hyperglycemia have been rare. Episodes of hypoglycemia have been more frequent, but only in the last six weeks since his left

knee surgery and have been caught quickly and resolved. He attributes the low readings to

increased exercise and therapy after his left knee replacement and having less of an appetite

while taking pain medications. He had one very low blood glucose in the pre-operative period

before his last surgery, which was resolved with a glucagon intramuscular injection. Despite

these findings, his lab results show that his blood glucose over time has been well-managed,

which has decreased his risk for complications.

Diabetes predisposes an individual for microvascular and macrovascular complications

and comorbidities. Microvascular refers to the smaller blood vessels of the body and include

complications such as retinopathy, nephropathy, and peripheral vascular disease leading to

amputations. Diabetes also puts patients at risk for macrovascular disease such as

cardiovascular disease, so management of cardiovascular risks is very important. This same

patient has a history of hypertension, hyperlipidemia, and tobacco use. To manage these

diseases, he is taking Losartan 10mg daily, Simvastatin 80mg daily, and aspirin 81mg daily. He

continues to smoke 1 pack per day, and smoking cessation efforts have been addressed. He has

annual visits with a cardiologist to monitor for heart disease, and he sees endocrinology and his

primary care physician where he has his blood work monitored on a regular basis.

This patient's physical exam revealed grossly normal findings, except for an elevated

blood pressure of 158/94, which came down towards the end of the exam. He also had some

swelling and limited range of motion of the left knee due to previous surgery. Because this

patient has been well-managed, adhering to his medications, utilizing insulin pump therapy,

and following recommendations for diet and exercise, he was cleared for his upcoming surgery.

He was also advised to adhere to strict monitoring of finger stick blood glucose measurements

in the perioperative and post-operative phase due to a history of hypoglycemia prior to his last surgery related to decreased oral intake and during recovery due to increased exercise. He will follow up with the surgeon at two weeks and six weeks post-operatively. He will also see his endocrinologist every six months for diabetic management and his primary care provider every year for a physical and chronic disease management. The patient was agreeable to this plan.

Literature Review

Insulin pump therapy is a viable option for the brittle, type 1 diabetic population. It has been shown to be safe, improve patient outcomes, and be cost effective due to insurance companies' willingness to cover all or part of this therapy (Misso, Egberts, Page, O'Connor, & Shaw, 2010). Intensive glucose control also reduces the overall risk of microvascular complications and major macrovascular outcomes such as heart attack and stroke (Fullerton et al., 2014). According to the Centers for Disease Control and Prevention (2016), in the United States, 29.1 million people have diabetes which may also be considered as one out of eleven people. Of those individuals, nine out of ten have type 2 diabetes. Being that type 2 diabetes has become prevalent in our population, a literature review was performed in an attempt to discover whether insulin pump therapy versus multiple daily injections of insulin in the patient with uncontrolled type 2 diabetes improve patient outcomes in terms of effectiveness, safety, and cost-efficiency.

To answer a therapy-related question such as this, the strongest evidence would come from systematic reviews, randomized control trials (RCTs), or meta-analyses of all the current related RCTs. Using the University of North Dakota's Harley E. French Library of Health

Sciences, a variety of databases were accessed including Cochrane Library, Cumulative Index to

Nursing and Allied Health Literature (CINAHL), and PubMed.

First, a search was performed on the Cochrane Library Database in order to find

systematic reviews. Medical subject headings, or MeSH terms, "diabetes mellitus" and "insulin

pump therapy" revealed 402 articles to review; 17 of which were categorized as systematic

reviews, 15 other reviews, 356 trials, 10 technology assessments, and four economic

evaluations. Three reviews pertinent to the topic were kept for consideration, while limiting

the search further. Next "diabetes mellitus type 2" and "insulin pump therapy" were keyed in

as MeSH terms. This search produced 28 results including six systematic reviews, two other

reviews, and 20 trials. The systematic reviews were duplicate matches of the search prior. Out

of this search, four trials were extracted for interpretation.

CINAHL was the next database to be accessed. MeSH terms "insulin pump therapy"

with Boolean phrase, *AND*, and "type 2 diabetes" was searched. This search was limited to

peer-reviewed articles, published dates between the years 2008 through 2016, and adult age

group only. This search revealed 92 results, of which six were saved.

Lastly, the PubMed database was accessed. Search terms included were "insulin pump"

and "type 2 diabetes" with a limit placed on articles published in the last five years. This

yielded 44 articles, of which three were kept. In summary, a total of 16 articles were obtained

for review. A summary of findings is discussed in the following sections.

Effectiveness of Continuous Subcutaneous Insulin Infusion (CSII)

In order to determine the effectiveness of an insulin or medication regimen and judge

how controlled blood glucose remains for a diabetic patient, glycated hemoglobin (hemoglobin

A1c) is monitored. A value of <7% to <8% is preferred and individualized for each patient. An

objective of *Healthy People 2020* is to reduce the proportion of persons with diabetes with a

hemoglobin A1c value greater than 9.0% from 17.9 percent of adults to 16.1 percent of adults

(Office of Disease Prevention and Health Promotion, 2014). Effectiveness of insulin therapy can

thereby be determined by monitoring A1c levels and obtaining a reduction in percentage from

previous readings, aiming for a goal of <8%.

     A pilot study published by Wolff-McDonagh et al. (2010), found significant reduction of

A1c with an average of 9.4% at initiation to 8.2% after one year of insulin pump therapy.

Following this study, a separately published analysis noted that after a 16-week course of

insulin pump therapy in sub-optimally controlled type 2 diabetic patients, A1c decreased from

an average of 8.4% to less than 7% in 90 percent of the patients (Frias et al., 2011). Similarly, an

analysis of continuous data over three years of insulin pump therapy in the type 2 diabetic

patient shows an overall reduction of A1c from an average of 9.66% to 8.71% (Jankovec et al.,

2010). Although these results are promising, the reproducibility of the results suggest

otherwise due to the limited sample sizes of 15, 21, and 54 patients respectively.

     Generally speaking, the research for use of insulin pump therapy in this population of

patients is lacking and outdated. The first RCT, which was comprised of 127 patients,

comparing MDI to CSII was published in 2003 and found that glycemic control was improved by

switching a patient from limited insulin therapy to intensive insulin therapy either by MDI or

CSII (Raskin et al., 2003). The CSII group in the Raskin et al. study had a more significant

reduction in A1c than the MDI group, and also reported satisfaction in the use of CSII due to

convenience and ease of use. In 2005, another randomized controlled trial (RCT) was published

to determine effectiveness of insulin pump therapy in the obese, uncontrolled type 2 diabetic

patient. This trial was composed of 40 patients, which were equally distributed to the insulin

pump therapy group or multiple daily injection (MDI) group. Results again determined that

insulin pump therapy was superior to MDI in decreasing A1c levels (Wainstein et al., 2005).

More recently, a larger scale RCT labeled, OpT2mise, was published in 2014. This RCT

started by optimizing MDI therapy on the entire group, then randomly assigning and comparing

a group of 163 patients optimized on MDI versus a group of 168 patients with insulin pump

therapy. At initiation, average A1c was 9.0% and decreased to 7.9% in the insulin pump group

and to 8.6% in the MDI group after six months (Reznik et al., 2014). Not only did this study

determine that insulin pump therapy can be effective in type 2 diabetes, but it also identified

appropriate candidates for this type of therapy because despite intensification and optimization

of MDI, their A1c levels did not show much improvement until placed on insulin pump therapy.

Comparing the findings listed above, insulin pump therapy does appear to be an

effective option in treating the patient with uncontrolled type 2 diabetes. Another finding of

interest in the OpT2mise trial and significant to the next topic of safety is that, "in the overall

patient population, the decrease in glycated hemoglobin was independent of diabetes duration,

body-mass index, education level, Montreal Cognitive Assessment score, and number of blood-

glucose self assessments done per day" (Reznik et al., 2014, pg. 1268).

Safety Issues with CSII

Insulin use, whether by MDI or by CSII, involves certain risks. Insulin is a medication

designed to lower blood glucose. For a number of reasons, insulin injection or infusion can

cause blood glucose to become dangerously low. With a continuous infusion of insulin,

hypoglycemia is a possibility and can become severe quickly if not addressed. Fortunately,

Resnik et al. (2014), Wainstein et al. (2005), Jankovec et al. (2009), and Frias et al. (2011),

conclude that severe hypoglycemia is not significantly increased when using CSII for type 2

diabetes. It was also found that the time spent in hyperglycemia was lessened due to the

continuous basal rate of insulin and proper bolus doses given at meal times (Resnik et al.,

2014). These findings are important because the reduction of time spent in hyperglycemia

contributes to the reduction of complications associated with diabetes mellitus. In addition,

the risk of hypoglycemic events is low for patients with type 2 diabetes which rationalizes that

this therapy is safe. The next safety concern entails operation of insulin pumps.

Ability to operate and troubleshoot the insulin pump has been considered a risk for

therapy. As stated previously, the OpT2mise trial found by chance that the decrease in A1c was

independent of Montreal Cognitive Assessment scores. "38% of patients in the pump therapy

group had mild cognitive impairment" (Reznik et al., 2014, pg. 1270) and were still able to

efficiently use the insulin pump. Also, with the advancement in technology, newer pumps are

more reliable, and have alarms for empty cartridges, low batteries, and occlusion of tubing or

faulty electronics (Cummins et al., 2010). Therefore, with proper education on usage of insulin

pumps and the automated mechanisms in place for the insulin pump user, safe use of this

technology is possible.

Despite being able to effectively use the pump, Meade and Rushton (2013)

administered a pump assessment questionnaire to 89 patients and found common areas of

deficiency of pump use including, "expired or no basal insulin prescription or insulin syringes in

the event of pump failure or removal, no mupirocin prescription for suspected site infections,

and lack of in-date glucagon kits". The results from this questionnaire demonstrate that

appropriate education and periodic assessment of pump users is a necessity in order to ensure

continued safety while using CSII due to the complications that may arise when depending on

technology for insulin administration.

Overall, CSII can be considered a safe therapy for patients with type 2 diabetes relative

to MDI being that episodes of hypoglycemia are insignificant and use of the insulin pump is safe

with appropriate education. Because the patient with insulin pump therapy requires a certain

amount of education and follow-up, resource utilization will be discussed in the next section in

regards to cost-efficiency.

Cost-Efficiency of CSII

Currently, "Medicare and private insurance companies place multiple restrictions on

coverage for insulin pump therapy in type 2 diabetes, thereby effectively denying access to this

treatment tool" (Wolff et al., 2010, pg. 658). Although previous trials have demonstrated that

insulin pump therapy is effective in reducing A1c levels, cost-effectiveness of this therapy must

also be acceptable for policy change to occur. Direct costs for diabetes include medical goods

and services and totaled $176 billion in 2012; Indirect costs are accrued from lost workdays,

restricted activity, disability, and early death and totaled $69 billion in 2012 (Centers for

Disease Control and Prevention, 2015). In order to determine if CSII would be cost efficient for

the patient with type 2 diabetes, the cost of MDI and the cost of long-term complications of

uncontrolled type 2 diabetes need to be compared.

There is insufficient research regarding whether CSII therapy is more cost-efficient than

MDI. Wolff et al. (2010) compared the cost of MDI versus CSII based upon the amount of daily

insulin usage. The study found that patients requiring a basal amount of insulin of 150 units or more per day had the benefit of a cost savings of approximately $12,000 over four years if using CSII, while using any less than 150 units per day did not prove to be cost-effective. The small sample size of 15 patients in this study makes it difficult to generalize these cost savings. Regardless of the small sample size, the projections of cost for each category of basal insulin usage is significant enough to gain attention and potential follow-up research.

A meta-analysis published in 2010 states that CSII is only cost-effective when there are moderate gains in reduction of A1c (at least 0.9% decrease from an 8.8% baseline) or when the use of CSII versus MDI reduces episodes of hypoglycemia by 50% (Cummins et al., 2010). This meta-analysis does carry a benefit in that it considers the cost savings from reduced complications and treatment of co-morbidities as a result of better glycemic control, but the information collected was between the years 2002 and 2007 with numerical values representative of healthcare in the United Kingdom, not the United States. The pilot study by Wolff et al. (2010) does not include figures regarding complications, and figures were based on American currency and average costs of treatment in 2010. In order to get a better picture of cost savings, analysis on current health care costs for diabetes and its complications should be developed.

An area that should also be considered when discussing costs of care for the diabetic patient is healthcare resource utilization. In a large claims analysis published in 2010, it was found that "after CSII initiation in the type 2 diabetic, the number of anti-diabetic drugs decreased by 46%, the rates of emergency department visits and inpatient admissions significantly decreased, and the rate of ambulatory visits significantly increased" (Lynch et al.,

2010). The increase in ambulatory visits is likely due to increased need for education on use of

CSII, and not from disease progression due to the decrease in hospitalizations in this group.

Costs for emergency and inpatient care are considerably higher than for outpatient visits, so

eliminating this resource utilization is a significant factor in healthcare expense. Again,

although these results are significant, this is the only large-scale analysis that reviews cost of

insulin therapy versus diabetic complications.

Conclusion and Learning Points

Conclusions drawn from this literature review include that CSII therapy versus MDI for

the uncontrolled type 2 diabetic patient can be effectively and safely used in patients.

Continuous subcutaneous insulin infusion versus multiple daily injections of insulin proved to

reduce hemoglobin A1c, even after optimization of MDI therapy took place. CSII is safe both in

regards to an insignificant number of hypoglycemic episodes related to this occurrence in the

MDI treated populations, and due to the findings that insulin pumps are easy to use even for

individuals with mild cognitive impairment. When discussing safety of insulin pumps, education

of their use is key, but should be considered alongside the cost of therapy being that pump

education is an area of resource utilization.

The cost of CSII is a topic of concern. At this point, Medicare and private insurance

companies are not convinced that this therapy is beneficial for cost savings and thus will not

cover this service. The pilot study previously discussed, did determine a cost savings for the

patient with type 2 diabetes if they were currently using a large amount of insulin with MDI.

More research and policy initiatives would be of benefit to determine the actual cost of therapy

versus cost of complications due to poor glycemic control. In one analysis, there were

significant reductions in emergency department visits and hospitalizations due to diabetes after

insulin pump initiation, but there was an increase in ambulatory visits which changes the

allocation of resource utilization for this group of patients. The cost-efficiency of insulin pump

therapy versus MDI can therefore not be determined with this limited amount of information.

The patient previously discussed as part of the case report is a type 1 diabetic patient

who benefits from CSII versus MDI. His glycemic control is adequate at this time with an A1c of

7.0% and he has no diagnoses related to complications from his diabetes. While he did report

ease of use of his insulin pump, he did note that episodes of hypoglycemia in the last six weeks

were more frequent. This, however, is likely due to an increase in activity with physical therapy

following his left knee replacement surgery. Cost for this patient cannot be compared to the

cost for a patient with type 2 diabetes, because this patient has type 1 diabetes and his insulin

pump therapy cost is covered by his insurance carrier.

Knowing that this patient transitioned from an uncontrolled state of diabetes to

attaining glycemic control after insulin pump therapy initiation, shows the increased

effectiveness CSII therapy. Research for the use of CSII in the uncontrolled type 2 diabetic

patient is promising in regards to effectiveness and safety, yet limiting in the scope of cost-

efficiency. The following learning points can be made from the findings of this case report and

literature review:

- Continuous subcutaneous insulin infusion therapy (CSII), or insulin pump therapy, is an

  effective tool in attaining glycemic control and limiting episodes of severe hypoglycemia

  and hyperglycemia for type 1 diabetics and should be considered for patients with

  uncontrolled type 2 diabetes.

- CSII is a safe therapy given proper education on use and maintenance of the insulin pump and instructions on what do if the pump fails.

- Although Medicare and private insurance companies are willing to defer the cost of insulin pump therapy for type 1 diabetic patients, they have restrictions on cost coverage for type 2 diabetes. Additional research is warranted that analyzes the cost accrued from the many complications and co-morbidities from type 2 diabetes to see if this outweighs the annual cost for CSII.

- Until proper cost analysis can be performed, the use of CSII in the uncontrolled type 2 diabetic patient, while beneficial for a patient's health, may be severely limited due to inability to pay for the cost of insulin pump therapy.

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