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Insulin Pumps in Diabetes Management
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Controlling diabetes is one of the most important challenges facing patients and dietitians alike, and healthcare practitioners are always looking for new ways to maintain glycemic control through more efficient and pain-free therapies. One of those therapies is the insulin pump, which may be the answer for some patients, including those with insulin-dependent type 2 diabetes.

The benefits of glycemic control in reducing complications of diabetes have been documented: The Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS), published in 1993 and 1998, respectively, often are cited as the most important large-scale studies that demonstrate the benefits of tight glycemic control in managing type 1 (in the DCCT) and type 2 diabetes (in the UKPDS).[1-3]

The DCCT study also proved the effectiveness of continuous subcutaneous insulin infusion (CSII), otherwise known as insulin pump therapy, in establishing good glycemic control and preventing complications in patients with type 1 diabetes. Nearly one-half of the intensively treated participants in the DCCT study were managed with CSII.[1] All the participants in this study had type 1 diabetes.

Because the DCCT and the UKPDS studies demonstrated the benefits of tight glycemic control in reducing complications for patients with both type 1 and type 2 diabetes, healthcare practitioners began considering CSII as a viable treatment option for individuals unable to achieve tight control through other treatment modalities.[1,4,5]

CSII was first used to treat patients with type 1 diabetes in the late 1970s.[2] Since then, insulin pumps have evolved considerably, with the newest generation of "smart pumps" capable of more closely mimicking normal physiologic insulin action. Indeed, the ultimate goal of the modern insulin pump is to produce excellent, nearly normal glycemic control without frequent hypoglycemia, which was a consequence of intensive insulin therapy in both the DCCT (multiple daily injections [MDIs] of insulin and CSII) and UKPDS (MDIs).[1,2]

The insulin pump market is rapidly expanding worldwide.[1-6] Because of improved pump technology and the increasing popularity of CSII, dietitians working in a variety of settings will undoubtedly encounter someone using a pump. Therefore, it's good to have some basic knowledge about insulin pump use and operation. After working with patients using the pump, many dietitians also decide to become certified pump trainers (CPTs), thus expanding their knowledge of diabetes management as well as augmenting career opportunities.

This continuing education course will evaluate basic insulin pump operations and discuss issues concerning proper candidate selection, the pros and cons of CSII, research regarding the effectiveness of CSII vs. MDIs, current pump models available, and potential safety issues with insulin pumps.

Insulin Pump Basics

Insulin pumps are about the size of a pager. Insulin is stored in a disposable cartridge and delivered into the body through a small catheter inserted into the subcutaneous fat layer. The catheter, which is part of an infusion set, and the insulin reservoir are removed and changed every two or three days. Infusion-set attachment sites are the same as those recommended for MDI therapy: in the subcutaneous fatty layer on the abdomen, back of the arms, upper buttocks, and thighs. Infusion set site locations are rotated just as injection sites are rotated in MDI regimens to optimize insulin absorption and prevent injection site cell hypertrophy.

An insulin pump delivers insulin in a manner that resembles normal physiologic insulin secretion. To accomplish this, the pumps are programmed to deliver rapid-acting insulin (insulin lispro, aspart, or glulisine) or short-acting regular insulin in two basic ways. First, the pump is programmed to release a small amount of basal insulin into the body at a variable hourly rate over 24 hours. This method of delivery mimics normal pancreatic basal insulin secretion. Second, insulin can be delivered as a bolus dose at meals to mimic prandial insulin secretion and as a correction dose to address an episode of hyperglycemia.

Patients can program and operate an insulin pump in a way that meets their ever-changing daily insulin needs by suspending, changing, or temporarily altering their basal and bolus insulin delivery based on life events or circumstances. For example, some patients need a slightly higher rate of basal insulin delivery in the early hours of the morning, when they're sleeping, and when blood sugar levels typically begin to rise.6 The patient can program the basal rate on his or her pump to deliver extra insulin automatically at this time, as would occur with normal pancreatic function.

The Right Candidates

Insulin pump therapy isn't for everyone, and guidelines exist to help patients and practitioners determine whether CSII is a good treatment option for individuals with either type 1 or insulin-dependent type 2 diabetes. Issues patients and practitioners should consider before transitioning to insulin pump therapy are as follows[3]:

- MDI no longer helps the patient meet individual treatment goals.
- The patient frequently experiences severe hypoglycemia (below 55 mg/dL) and has hypoglycemia unawareness or both.
- The patient experiences frequent and unpredictable fluctuations in blood glucose levels.
- The patient is physically and cognitively able (or has a reliable caregiver who's able) to change infusion sets, fill pump cartridges, and program and troubleshoot the pump.

- The patient is willing and eager to learn a new way to manage his or her diabetes and to invest the time needed to learn how to use the pump.

- The patient has the skills needed to count carbohydrates.

- The patient is willing to test blood glucose levels six to eight times daily, at least initially.

Patients and caregivers also should understand that learning to use a pump and fine-tuning the programming and settings takes time, effort, and perseverance by everyone involved.

Choosing the Right Insulin Pump

The following pump models are currently available in the United States: Animas OneTouch Ping, Medtronic Revel, Accu-Chek Combo, Insuletis Omnipod, Tandem's t:slim, and SOOIL's DANA Diabecare R.

A patient considering pump therapy should review the available options with his or her diabetes practitioner or a certified diabetes educator who's familiar with all the insulin pump models and who can decide which one is best for the patient. Some important things to consider when choosing a pump include visual appeal, ease of use (button size, setup procedure, etc), screen readability (especially for individuals with poor vision), special features (such as a database to help with carbohydrate counting), tubeless pump options, any extra cost for supplies, and available insurance coverage if a patient is seeking reimbursement. A patient should consider his or her lifestyle and whether carrying or otherwise being attached to a pump will help or hinder quality of life and glycemic control.

The availability of local certified pump trainers (CPTs) or endocrinologists experienced with a particular pump also is important to consider, as professional guidance is essential for most patients. Pump trainers can be particularly important in rural areas, where endocrinologists often aren't available to help patients with hands-on pump instruction. CPTs usually work with a patient's endocrinologist or primary care provider to set individual glucose goals and insulin pump settings. All CPTs are fully trained by insulin pump manufacturers to initiate and fine-tune CSII using their particular pump. This is important, as manufacturers ensure that CPTs are proficient in intiating and fine-tuning therapy with the specific pump patients are using. Manufacturers also offer ongoing training and support for pump trainers to provide the best care and guidance to patients. Most companies require recertification (every one to two years) to ensure high-quality patient care.

Moreover, CPTs often are certified to train on a variety of pumps so they can serve a greater number of patients. CPTs may work privately or with outpatient diabetes clinics, hospitals, or endocrinologists. Pump manufacturers usually pay CPTs or the facilities at which they work for the initial and follow-up training time spent with patients. However, companies often will pay trainers for a limited number of hours they spend with patients. Therefore, patients need to speak with their diabetes practitioner about long-term support. If needed, pump manufacturers often are willing to pay for extra training time. The good news is that many patients can continue working with an endocrinologist or diabetes educator who's certified as a pump

trainer to adjust insulin pump settings after the initial training and can obtain insurance coverage for this service.

Learning to Use an Insulin Pump

Patients transitioning to pump therapy should spend several hours with a certified diabetes educator to learn the skills necessary to safely operate a pump. Patients should learn how to accurately count carbohydrates, frequently monitor blood glucose, and respond to episodes of hyper- and hypoglycemia before starting pump therapy.

Once a patient receives the pump he or she has chosen, a CPT will provide hands-on training in basic pump operation. The patient will learn about infusion set and cartridge changes, and site selection and rotation as well as review safety concerns and troubleshooting. During the initial training session, the CPT will program the pump with the patient's individual basal and bolus settings. In follow-up training sessions, the CPT may help the patient adjust the pump settings and learn more advanced pump techniques, such as altering the bolus insulin delivery rate.

In addition to the educational materials the patient's CPT provides, there are a variety of free materials available from the insulin pump manufacturers. Patients should be directed to review these materials before, during, and after the initial training to get the best results. Materials usually are offered online, in DVD/CD format, and in print. Pump patients also should be encouraged to take advantage of free pump optimization classes offered by their diabetes practitioner or many of the pump manufacturers. Proper training and ongoing follow-up, education, and guidance are the keys to safe and optimal pump use.[3,6]

Comparing Outcomes: CSII vs. MDIs

MDI therapy for diabetes typically involves one or two daily injections of a long-acting insulin analog or intermediate-acting insulin combined with short- or rapid-acting insulin injections at some or all meals.

Since 2000, long-acting insulin analogs have progressively replaced NPH insulin in MDI therapy.[7,8] Long-acting insulin analogs have a more predictable absorption profile, resulting in fewer episodes of both hypo- and hyperglycemia compared with NPH.[9] Similarly, rapid-acting insulin analogs often are preferred over short-acting regular insulin in MDI therapy because of more predictable absorption, duration, and action.[8]

Studies comparing CSII with NPH-based MDIs demonstrate improved outcomes with CSII. The 5-Nations trial compared overall glycemic control, frequency of hypoglycemic events, and self-assessed quality of life among 272 patients with type 1 diabetes treated with either CSII or NPH-based MDIs for six months. Individuals using CSII in this study scored significantly higher on a diabetes quality of life questionnaire than those being treated with MDIs. Researchers also found that CSII resulted in lower hemoglobin A1c along with a statistically significant reduction in the frequency of both mild and severe hypoglycemic events when compared with NPH-based MDI. This is an important finding, as frequent hypoglycemic episodes will lower A1c, producing an artificial appearance of improved overall glycemic control.[10]

A more recent meta-analysis suggests that CSII is especially beneficial for patients using NPH-based MDI therapy who suffer from frequent severe hypoglycemia, defined in different studies as a hypoglycemic episode during which an individual needs assistance, IV glucose infusion, or glucagon; hypoglycemia resulting in seizure or coma; hypoglycemia causing disorientation and uncontrollable shaking or crying; and/or a blood glucose level below 50 mg/dL, a potential consequence of intensive MDI therapy.[11]

Indeed, a major benefit of CSII over NPH-based MDI therapy seems to be a reduction in both the frequency and severity of hypoglycemia.[10,11] NPH insulin is associated with more nocturnal hypoglycemic episodes compared with the long-acting insulin analogs detemir and glargine.[12,13] Similarly, rapid-acting insulin analogs reduce the frequency of nocturnal hypoglycemia compared with regular insulin.[12,13]

The superior action and predictability of insulin analogs likely explains the less consistent results of studies comparing CSII with MDIs using long- and rapid-acting insulin analogs. In fact, a recent comparison of insulin glargine- and lispro-based MDIs and CSII in a randomized, multicenter study found that glycemic control was equivalent in both groups.[7] The incidence of nonsevere hypoglycemia was similar between the two groups, and severe hypoglycemia was rare. However, this study was small (n = 43), and the authors noted that the population they worked with didn't include patients with type 1 diabetes who might have special indications for CSII, such as a long duration of disease with low insulin requirements or hypoglycemia unawareness with frequent, severe hypoglycemia on MDI therapy.[7]

Another study comparing CSII and glargine-based MDIs in young children aged 1.7 to 6.1 with type 1 diabetes also found no difference in glycemic control between the groups.[14] The authors noted, however, that the glycemic targets for both groups were set high (A1c of 7.7% to 8.5%), as is appropriate for this age group. Therefore, CSII may produce comparable glycemic outcomes compared with MDI without increased risk of hypoglycemia in this young population.

In a thorough examination of evidence comparing the effectiveness of MDIs and CSII in both type 1 and type 2 diabetes, Pickup and Renard concluded that "there is no doubt that a proportion of type 1 diabetic patients who are poorly controlled on [NPH]-based MDI regimens are helped by switching to glargine or detemir; nocturnal mild or moderate hypoglycemia and fasting hyperglycemia may be reduced."[8] Consequently, these researchers do support a trial of insulin analog-based MDI therapy for patients with poor control before considering CSII, as this may provide better control and fewer episodes of hypoglycemia than NPH-based MDI. However, they also cite several randomized controlled studies that showed no improvement in A1c when patients switched from NPH- to analog-based MDIs.[15-17] Therefore, CSII may be a superior treatment option in patients who don't see improvement after changing the type of insulin used in MDIs.[8]

In support of CSII, two small head-to-head randomized comparisons of insulin analog-based MDI regimens with CSII confirmed the view that pump therapy can achieve improved glycemic control compared with insulin analog-based MDIs. Doyle and colleagues treated 32 patients aged 8 to 21 with type 1 diabetes with aspart- and glargine-based MDIs or CSII over 16 weeks.

The data showed significantly lower A1c results with CSII (-0.9% vs. -0.1%).[16] Premeal glucose levels also were significantly lower in the CSII group.

Similarly, Hirsch and colleagues randomized 100 patients older than 18 to glargine-based MDIs or CSII for two periods of five weeks, with the results showing significantly less glucose variability with CSII. (A1c wasn't measured over this short period of time.) Specifically, CSII-treated patients had significantly more glucose readings greater than 80 mg/dL but less than 140 mg/dL than MDI-treated subjects (43% vs. 33% of readings for the CSII vs. MDI subjects) as measured by a continuous glucose-monitoring device. Also, the CSII-treated subjects had fewer readings greater than 140 mg/dL (41% vs. 50% of readings for CSII vs. MDI). The percentage of glucose readings below 80 mg/dL was similar for both treatments (175 of all readings for both CSII- and MDI-treated subjects).[17]

In a small 2005 study (n = 27), Pickup and colleagues sought to determine whether hypoglycemia-prone patients aged 29 to 49 with type 1 diabetes could achieve better blood sugar control by switching from NPH-based MDIs to treatment with insulin analog-based MDIs or CSII.[18] Indeed, some patients could improve glycemic control with insulin analog-based MDIs, and these patients continued this therapy. Patients who couldn't lower their A1c when they switched from NPH- to insulin analog-based MDIs were then treated with CSII. In this group, CSII did produce a significant change in A1c (average reduction of 1.4%). Also of note was the reduction in glucose variability (fewer glucose readings outside of the optimal 80 to 140 mg/dL range throughout the day) and the reduced number of hypoglycemic episodes when these patients used CSII vs. MDIs.

In a later study, Pickup and colleagues determined that the improved A1c values achieved by patients switching from MDIs to CSII likely were due to reduced glucose variability within and between days.[19] Patients being treated with CSII experienced fewer extreme glucose excursions (typically from hyperglycemia after meals and/or hypoglycemia between meals and overnight) and more consistent glucose control from day to day than patients being treated with insulin analog-based MDIs. Reduced glucose variability in patients treated with CSII has been attributed to the ability of pump therapy to mimic normal insulin action and release.[18,19]

Managing CSII in Type 2 Diabetes

Patients with insulin-requiring type 2 diabetes usually are treated with one or two daily injections of long-acting insulin, combined initially with oral hypoglycemic agents (usually biguanides).[8] MDI therapy with short- or rapid-acting insulin at meals often is initiated and oral hypoglycemic agents discontinued when this combination fails to maintain good glycemic control. This transition from oral medications to insulin therapy in patients with type 2 diabetes is thought to be due to the progressive nature of type 2 diabetes and resulting insulin deficiency in some patients.[8]

CSII may be a viable treatment option for some patients with type 2 diabetes who don't benefit from MDI, but study results are equivocal.[1,8,20-23] Herman and colleagues compared CSII with glargine-based MDI therapy in patients with type 2 diabetes (n = 107).[20] No significant differences in A1c, frequency of hypoglycemia, quality of life, or weight gain were noted between the two groups.

A 24-week study by Raskin and colleagues (n = 127) also demonstrated similar A1c outcomes between CSII and NPH-based MDIs but noted that glucose levels after breakfast were significantly improved with CSII. In addition, 93% of CSII-treated patients in this study preferred CSII for its convenience, improved flexibility, and ease of use. Subjects in this study who had type 2 diabetes for two or more years were CSII naïve and treated with at least one dose of insulin per day (regular insulin lispro NPH, premixed insulin, Lente, or Ultralente) with or without oral diabetes medications.[21]

In contrast to these studies, an 18-week crossover trial by Wainstein and colleagues involving 40 obese, insulin-dependent subjects with type 2 diabetes did show improved A1c as well as lower postmeal glucose levels with CSII compared with NPH-based MDIs.[22]

In light of this evidence, individuals with type 2 diabetes also can be good candidates for CSII. Pickup and Renard noted that active individuals who need a flexible insulin regimen and patients struggling with postprandial hyperglycemia may experience improved control with CSII.[8] In addition, just like individuals with type 1 diabetes, patients with insulin-requiring type 2 diabetes may experience a much better quality of life with CSII, an important consideration when choosing treatment options. Indeed, more research is needed to determine whether other patient characteristics make CSII a preferred treatment option for type 2 diabetes.[1,8]

Insulin Pump Pros and Cons

One clinical advantage of CSII over MDIs may be less glucose variability, meaning patients experience less frequent episodes of postprandial hyperglycemia and fewer episodes of hypoglycemia throughout the day.[9,19,24,25] They have fewer daily excursions outside the optimal glucose range for diabetes (80 to 140 mg/dL).[9,19,24,25] Other advantages, as demonstrated in the studies mentioned above, are the reduction in the number and severity of hypoglycemic episodes and improved A1c.[3,10,11,18,19] Patients often cite quality of life as a reason to begin using CSII, which may include improved flexibility in the timing and selection of meals and the ability to reduce basal dose when exercising.[1,6]

Some disadvantages to pump therapy may include the extra cost of the insulin pump and supplies; time and trained personnel needed to initiate, supervise, and fine-tune the therapy; and the level of patient participation and motivation needed to optimize CSII.[1,8]

Patients using CSII also may be at risk of more rapid (but not more frequent) development of diabetic ketoacidosis if insulin delivery is suspended or interrupted for an inordinate period of time.[3,8] Patients using MDI therapy have a subcutaneous store of long-acting insulin that may slow the development of diabetic ketoacidosis. In contrast, CSII uses only rapid-acting insulin that's active in the body for four to six hours, so if basal insulin delivery is interrupted for too long, blood sugar levels can rapidly rise.[8] In addition, over time, CSII users may have issues with infusion site infections or irritation, poor infusion set adhesion, and inadequate insulin absorption.[1,3,6] Patients can minimize these issues by keeping regularly scheduled appointments with their diabetes practitioner or educator who has expertise in using this technology.

Safety Concerns and How to Alleviate Them

In 2008 and 2009, the FDA convened panels of insulin pump experts who concluded that insulin pumps generally are safe and effective for managing diabetes.[24,25] However, they did identify potential safety problems in some aspects of insulin pump use, training, and design.

The panels agreed that many adverse events associated with CSII are caused by operator error. Some of the common safety problems include the following:

- damaging the pump by exposure to extreme temperatures or extended submersion in water;
- failing to notice disconnected infusion sets, which therefore aren't infusing insulin into the body;
- failing to reconnect an infusion set after disconnecting from the pump for a shower or physical intimacy;
- using an infusion set for more than three days;
- failing to properly rotate infusion sites;
- failing to frequently test blood glucose as recommended;
- overriding or improperly programming the bolus calculator software;
- forgetting to bolus; and
- guessing rather than counting carbohydrates at meals.

According to Judith Cope, MD, MPH, of the FDA's Office of Pediatric Therapeutics, from 1996 through 2005, the FDA received 1,594 reports of adverse events involving insulin pumps in patients between the ages of 12 and 21.[26] Of these reported incidents, 33% were related to equipment malfunction (eg, problems with alarms, catheters, and/or screen displays).[24] Thirteen deaths resulting from either hyper- or hypoglycemia were reported during this time period. Per this report, it isn't clear to what degree these deaths were due to insulin pump operator error or if some of the deaths were intentional. However, none of the deaths in the FDA report were attributed specifically to insulin pump malfunction.

The panel experts agreed that as insulin pumps become more sophisticated and their design more complex, additional safety features should be developed to prevent patient harm. Some design areas identified as potential safety hazards include display fonts that are too small to read, inadequate display backlighting, confusing display menus, and inaudible alarms.[24,25]

Safety features that can better detect and alert users of the over- or underdelivery of insulin (either from operator error or pump failure) also were recommended. For example, a pump that can detect air bubbles in tubing or alert a patient if an infusion set becomes dislodged might

significantly reduce incidents of severe hyperglycemia and diabetic ketoacidosis.[24,25] Overall, this safety report reinforces the value of good patient selection and training because many adverse events are attributed to operator error.

CSII or MDI: Which Is Better?
CSII offers some advantages over MDI therapy, but experts agree that properly selecting insulin pump candidates and adequately training them is key to experiencing optimal outcomes and patient success.

As CSII technology continues to advance and pumps can more closely mimic normal pancreatic function, new challenges and opportunities for patients and practitioners alike will arise. This is a great time for dietitians interested in diabetes care and education to increase their knowledge and skills in insulin pump operation, as the number of patients using CSII is likely to continue to grow.

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Examination

1. Why would a patient using continuous subcutaneous insulin infusion (CSII) be more prone to rapidly developing diabetic ketoacidosis than someone using multiple daily injections (MDIs) of insulin with long- and rapid-acting insulin analogs?
A. An insulin pump does not deliver basal insulin.
B. Insulin pumps often malfunction.
C. An insulin pump delivers only rapid-acting insulin.
D. All of the above

2. An insulin pump mimics normal physiologic insulin secretion in several ways, including which of the following?
A. Basal insulin can be delivered at a variable rate, depending on individual needs.
B. The patient can alter basal and bolus doses as a situation warrants.
C. The insulin pump monitors blood sugar levels 24 hours per day, just like the pancreas.
D. A and B

3. Some people with insulin-dependent type 2 diabetes achieve more optimal blood sugar control with CSII over MDIs. One such patient might be someone who:
A. has difficulty with multiple injection therapy.
B. has an active lifestyle and desires flexible diabetes management.
C. often suffers with postprandial hyperglycemia.
D. All of the above

4. Which of the following issues will CSII users not have to deal with over time?
A. Infusion site infections or irritation
B. Inadequate insulin absorption
C. Increased glucose variability
D. Poor infusion set adhesion

5. Which of the following is a major advantage of CSII over MDIs for the treatment of type 1 diabetes?
A. A reduction in the frequency and severity of severe hypoglycemia
B. Lower out-of-pocket costs
C. Ease of operation and a short learning curve
D. The need to check blood sugar less frequently

6. Two keys to safe insulin pump operation and good glycemic control are patient training (initial and ongoing) and appropriate patient selection.
A. True
B. False

7. CSII may be successful for which of the following types of individuals?
A. One who wants to test his or her blood glucose less often
B. One who already has optimal glycemic control with MDIs but wants more flexibility in his or her insulin regimen
C. One who understands that optimizing pump therapy takes time and perseverance
D. B and C

8. Poor glycemic control with CSII can result from operator error. Some of the most common errors made include which of the following?
A. Failure to properly rotate infusion set sites
B. Frequently overriding insulin pump bolus dose recommendations (settings may not be correct)
C. Forgetting to bolus at meals
D. All of the above

9. Experts at the FDA highly recommend that insulin pumps being developed include better alarm systems to alert patients when insulin delivery fails.
A. True
B. False

10. Patients with insulin-dependent type 2 diabetes usually are treated with one or two daily injections of long-acting insulin, combined initially with which class of oral hypoglycemic agents?
A. Biguanides
B. Alpha-glucosidase inhibitors
C. Meglitinides
D. Sulfonylureas