COMMENTARY

Insulin Pump Therapy Training and Management: An Opportunity for Community Pharmacists

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Continuous subcutaneous insulin infusion (CSII), more commonly known as insulin pump therapy, was first established in the marketplace in the 1980s and is now one of 3 currently available modalities for the delivery of insulin in managing diabetes.[1] Other modalities for insulin delivery include syringe-injected and pen-injected. In the United States in 2007, an estimated 569,000 patients, representing about 12% of patients taking insulin, used CSII for insulin administration; 75% used syringes and 22% used pens.[2] CSII users currently represent about 3% of the 17.9 million patients diagnosed with diabetes in the United States.[3]

What Is Insulin Pump Therapy?

Of all the insulin delivery modalities, CSII is the route that with optimal utilization most closely mimics the physiological actions of the pancreas.[1,4,5] The external device consists of a small battery-operated electromechanical pump that is programmed to deliver insulin stored in a small reservoir. Insulin is delivered by the pump in 2 ways: (a) as basal insulin, or insulin that is delivered at programmed rates throughout the entire day to match the individual's baseline insulin requirements, or (b) as a bolus that provides an additional boost of insulin to cover for ingested carbohydrates or elevated blood glucose levels. The amount of the insulin bolus is calculated using the pump and is managed by the patient.[1] Rapid-acting insulin, including lispro, aspart, and glulisine, is the recommended insulin for pump therapy because of improved absorption profiles.[5] Amounts of insulin as small as 0.025 units are delivered into the subcutaneous tissue from the pump through small tubing called a cannula. The insulin is then absorbed from the subcutaneous tissue at similar rates as when injected by syringe or pen.

Bolus insulin is provided by the pump in an on-demand fashion based on carbohydrate intake or varying degrees of hyperglycemia experienced by the patient. To calculate the amount of insulin to be delivered for carbohydrate intake, a commonly used method is to divide 500 by the patient's previous total daily dose (TDD) of insulin; for example, in a patient using 50 units (U) per mL per day, the insulin-to-carbohydrate coverage ratio is 1 U to cover 10 grams of carbohydrates.[6] For a bolus related to hyperglycemia, the pump uses a programmed insulin sensitivity factor, also known as a correction factor, to calculate the appropriate amount of insulin to lower the blood glucose level to an established target range. To calculate the correction factor, a commonly used approach for rapid-acting insulin is to divide 1,800 by the TDD, although various methods have been suggested.[7] In addition, initial basal and bolus rates are calculated based on the patient's pre-pump insulin usage requirements and are titrated according to the individual's response.

Advantages and Disadvantages of Insulin Pump Therapy

Current evidence for CSII in type 1 diabetes is well established. Most studies suggest that, compared with administration of insulin via multiple daily injections, CSII provides equivalent or better glycemic control using less insulin, with fewer and less severe hypoglycemic events.[1,4,5,8-10] Pickup et al.'s 2002 meta-analysis of 12 randomized controlled trials comparing CSII with multiple daily injections showed that CSII significantly improved glycemic control while reducing the required daily insulin dose by 14%.[8] In a 2004 meta-analysis, Retnakaran et al. concluded that among patients with type 1 diabetes treated with rapid-acting insulin analogs, CSII produced better glycemic control than did multiple daily injections; the improvement in hemoglobin A1c that was associated with CSII use was greater for patients with higher A1c at baseline.[9] Pickup et al. (2006) found that among patients with type 1 diabetes, those with poor diabetes control under multiple daily injections benefited from a switch to CSII to a greater degree than did patients who were well controlled with injection-administered insulin.[10]

The evidence for CSII in type 2 diabetes remains limited.[4,5,11-14] In Raskin et al.'s study of patients with type 2 diabetes, CSII and multiple daily injections were found to be equally efficacious and safe, but 93% of CSII users expressed a preference for CSII compared with their previous regimen of multiple daily injections.[13] Herman et al. compared CSII with multiple daily injections in a sample of patients aged 60 or older with type 2 diabetes; efficacy, rates of hypoglycemia, and weight gain were similar in the 2 treatment modalities.[11] A study by Wainstein et al. focused on CSII in a sample of obese patients with type 2 diabetes and found improvement in A1c over multiple daily injections without significant changes in weight, although goal A1c levels were not attained.[14] These studies suggest that CSII should be considered for type 2 diabetes patients requiring intensive insulin therapy,[15,16] but more studies are needed.

One clear advantage that pump therapy provides is the decreased number of syringe needle sticks that are required.[5] Once the cannula is inserted under the skin, it may be worn

in the same position for up to 72 hours. It is estimated that compared with multiple daily injections, which can require 4 or more injections a day, the number of annual syringe needle sticks decreases from approximately 1,460 to 156 when using an insulin pump. CSII also provides greater flexibility; for example, basal rates can be adjusted to correct for "dawn phenomenon," a period of high blood glucose in the morning.

Disadvantages also exist for pump therapy. Cost remains a large obstacle for many patients, with the initial cost of an insulin pump and supplies ranging between $4,995 and $6,500.[5,17,18] Because the insulin pump delivers only very small subcutaneous amounts of insulin analogues with a short activity life, there is an increased risk for developing diabetic ketoacidosis (DKA) if insulin delivery is interrupted. Because of this risk, it is important that patients self-monitor blood glucose frequently throughout the day;[1,4,19] thus, patients using insulin pumps may require as many finger sticks as patients using multiple daily insulin injections.[4] Fortunately, it has been shown that the rate of DKA with pumps has been reduced with proper pump education and management.[1,4] The most common complications of pump therapy are infusion site irritation, occlusion, or, occasionally, infection.[4]

Finally, CSII is a complex mode of insulin delivery when considering patient ease of use.[5] Patients under consideration as candidates for CSII should be evaluated closely to determine if they are capable and motivated to learn CSII techniques, which include carbohydrate counting and frequent self-monitoring (Table 1).[19] CSII is discouraged for patients who have a history of noncompliance with self-monitoring or current insulin regimens, significant psychological problems, or learning disabilities.[1,4,19] A review of 25 years of CSII provided a framework for considering pump therapy, concluding that "special expertise and adequate educational facilities are needed by the medical team to initiate and supervise pump patients."[1] Proper training of the patient is necessary to minimize the effect of the complexity of CSII in day-to-day care.

TABLE 1 Indications and Selection Criteria for Insulin Pump Therapy[a]

Indicators for Pump Treatment:
• Motivated to achieve normoglycemia
• Performs self-care responsibilities associated with diabetes
• Technical ability to monitor glucose and operate insulin pump
• Intellectual ability to learn and retain information
• Effective coping patterns
• Availability of support systems
• Financial resources to cover cost of therapy

[a] *Adapted from the American Association of Diabetes Educators Position Statement on Education for Continuous Subcutaneous Insulin Infusion Pump Users.*[19]

Community Pharmacists and the Insulin Pump Market

Although CSII was once primarily a tool utilized by endocrinologists and other diabetes specialists, it is reasonable to assume that more nonspecialty practitioners will be incorporating CSII into their practices, given the prevalence of diabetes in the United States—a record 23.6 million people, counting both diagnosed and undiagnosed cases, and an estimated 57 million individuals with pre-diabetes.[3] The potential for growth in the use of CSII by nonspecialists creates an environment and opportunity for pharmacists to work with them in the management of CSII.

Traditionally, training of pump patients is performed primarily by case managers employed by the pump manufacturer or by certified consultant pump trainers, such as registered nurses certified as diabetes educators. Pharmacists currently play a role in training patients in the proper use and administration of all insulin delivery modalities but are rarely involved in CSII training. Although the current count of pharmacists acting as CSII trainers is unknown, in 2003 the editor of a newsletter for medical professionals involved in diabetes care estimated that fewer than 20 pharmacists in the United States were certified to provide CSII education.[20] Growth in the market for CSII trainers creates an environment in which pharmacists can fill a need for high-quality education, training, and management for CSII.

In its position statement on CSII, the American Diabetes Association (ADA) indicates that CSII should be "prescribed, implemented, and followed by a skilled professional team familiar with CSII therapy and capable of supporting the patient."[21] Under the right conditions, the community pharmacy can operate as a convenient center of CSII support and information for the population of patients with diabetes that it serves. Community pharmacies are already established as a point of access for the dispensing of diabetes medications, including insulin and testing supplies such as strips, lancets, and glucose monitors. Enabling the pharmacist to act as an educator can improve the coordination of care and the efficient use of these medical tools. Many pharmacies also are providers of durable medical equipment, a role that positions them as a logical point of sale for the pump and monthly supplies.

The Causey Pharmacy Model for Insulin Pump Training and Management

Causey's Pharmacy is an independent community pharmacy that has been providing CSII training and management, using a systematic approach to CSII therapy initiation, since 2002. The pharmacy program is ADA recognized, and several of the pharmacists are Certified Diabetes Educators (CDEs). The goal of the pharmacist is to complete initial training and management in 2 months, but it may take up to 6 months in some complicated cases.

Patients who are potential candidates for CSII are identified by 3 mechanisms: (a) referral from the insulin pump manufacturer, (b)

referral from the treating physician, and (c) patient identification by the pharmacist educator during routine self-management training. Once a patient is identified as a potential CSII candidate, the pharmacist educator evaluates the patient's appropriateness for CSII. If the patient is considered an appropriate candidate, the patient and the family or support structure are invited to a session that introduces CSII. During this session, the advantages and disadvantages of CSII are discussed, followed by a demonstration of the insulin pump and infusion sets. At this point, if the individual accepts CSII, cost issues are evaluated and insurance paperwork is completed.

Once the patient has been approved for CSII by the insurance company, training is initiated. Pre-pump training is typically divided into 2 sessions, "Carb Counting" and "Button Pushing," but can be amended to meet the individual patient's needs and learning capacity. During "Carb Counting," the pharmacist educator introduces or reviews appropriate carbohydrate counting technique. At a subsequent visit, the patient's comprehension and skill are then assessed through a 3-day food diary reviewed by the pharmacist educator. Additionally, the pharmacist educator reviews self-management skills, such as treating hypoglycemia and hyperglycemia or maintaining glucose control during exercise and illness. During the second pre-pump session, referred to as "Button Pushing," the pharmacist educator reviews the technology and mechanics of working the pump; the session includes topics such as navigating the pump menus, setting insulin infusion rates, loading the insulin cartridge and priming the tubing, and day-to-day handling and functioning of the pump.

During pre-pump training, the pharmacist educator also gathers relevant patient information to determine starting basal rates and bolus settings, establishes a collaborative relationship with the prescribing physician, and works to obtain signed orders for initiation and titration according to an established protocol. The protocol delineates (a) the change in the patient's current insulin regimen within the first 24 hours prior to the pump start, such as how the basal insulin will be reduced prior to the pump start; and (b) how the pharmacist educator will make changes in the basal rates, the insulin-to-carbohydrate ratio, and the insulin sensitivity factor during the time period when the pharmacist manages the patient. The protocol also establishes a communication path through which the prescribing physician and pharmacist educator communicate during the management period.

During the "Button Pushing" training session, patients use normal saline to initially learn proper insulin cartridge loading and insulin pump priming. The patient may also be given the option of a saline trial session in which the pump is worn for a few days while normal saline is infused in place of insulin and the patient's injection regimen is continued. This is especially useful for patients who are apprehensive about pump therapy or have difficulty mastering the pump. After all pre-pump training is completed, the next step is the actual pump start. Prior to the pump start, the pharmacist educator instructs the patient on how to discontinue or adjust the current insulin regimen. During the pump start visit, many important learning issues for CSII are reinforced for the patient. The patient then self-loads the cartridge with rapid-acting insulin and an infusion set is inserted. The pharmacist educator also provides appropriate monitoring and follow-up schedules for the patient. Typically the first follow-up phone call is within 12 hours of the pump start.

Following the initiation of the pump, the patient reports back to the pharmacist educator on a daily basis until blood glucose numbers are stable and any patterns of hypoglycemia or hyperglycemia are corrected. This initial stabilization period can range from a few days to 1 week. After this initial titration period, the patient continues to report back to the pharmacist educator on a weekly basis for approximately 1 to 2 months. A follow-up visit is scheduled between 1 and 3 weeks at which advanced techniques of pump therapy are introduced to the patient. These techniques include use of dual wave boluses (i.e., setting multiple basal patterns based on basal insulin requirements throughout the day), the use of temporary basal rates, and pattern management.

During the initial weeks of CSII training, patients are taught how to perform basal testing. Basal testing is a systematic method for determining if the basal rates are set appropriately. Blood glucose is measured every 2 to 3 hours for a defined period of time during which the patient does not eat or use supplemental (bolus) insulin. The pharmacist uses these readings to determine the appropriateness of the basal rate and make adjustments according to protocol as necessary. Once basal testing is completed, the insulin sensitivity factor and insulin-to-carbohydrate ratio are tested and adjusted if needed according to protocol.

Sources of Reimbursement for Pharmacist Services

Multiple financial resources exist for the pharmacist who serves as a certified pump trainer. The pharmacist gains reimbursement directly through the pump company for the initial training and management at a fixed rate that covers up to 2 months of training and management. There is no patient financial responsibility for the training and management services for these 2 months. If any additional education or management is required by the patient after the 2 months of initial training, the pharmacist educator may bill the patient's individual insurance provider under diabetes education and self-management codes (Healthcare Common Procedure Coding System codes G0108 and G0109) provided that the pharmacist practices in an ADA-recognized program. Most patients will have cost-sharing that the pharmacist must collect in the form of deductibles or copayments.

TABLE 2 *Eligibility Requirements for Insulin Pump Trainers*[a]

Hold an active, unrestricted license in one of the following:
• Registered Nurse
• Pharmacist
• Doctor of Medicine or Doctor of Osteopathy
• Physician Assistant
• Licensed Occupational Therapist
• Podiatrist
• Optometrist
• Licensed vocational or practical nurse
OR
A minimum of a master's degree from a U.S. college or university accredited by a nationally recognized regional accrediting body in one of the following areas:
• Nutrition
• Health education
• Advanced degree in public health
• Social work
• Clinical psychology
• Exercise physiology

[a]*Adapted from the Medtronic Product Trainer Manual.*[23]

Qualifications and Time Commitment for Pharmacists Working as Insulin Pump Trainers

A growing number of pharmacists are trained and work as CDEs. Currently there are over 15,506 CDEs in the United States, the vast majority (96%) of whom are nurses and dietitians. As of 2007, the National Certification Board of Diabetes Educators has certified 691 pharmacists (about 4% of CDEs nationwide) who have successfully passed their examination and met their practice requirements to obtain the CDE credential; it is unknown how many of these are currently acting as CSII trainers.[22] Although certification as a CDE is not a requirement to become a certified pump trainer, it is highly recommended that pharmacists obtain their CDE if they are to provide CSII training and management. Additional instruction by the clinical staff of the insulin pump manufacturer is also helpful.

Current requirements for becoming a certified pump trainer, sometimes called a certified product trainer, are established by the insulin pump manufacturer. To be eligible for consideration, the individual must first possess a license in one of many health fields or hold a master's degree in a designated area as listed in Table 2.[23] The individual must study and understand the individual pump product as well as premises behind CSII and diabetes management, complete a hands-on training program, and demonstrate proficiency in training skills. Many companies also require the trainer to pass a written test with a minimum established score. The individual must also show proof of current professional liability insurance.

In addition to providing technical instruction to patients on the safe operation of insulin pumps, some pump trainers may also provide patient management and follow-up for a short period following training. These responsibilities should be discussed first with the prescribing physician. It is also important to note that pharmacist educators should perform responsibilities only within their scope of practice, which is governed by their respective professional licensing body. To aid in the management of patients, pharmacists may need to establish a collaborative practice agreement that delineates the role and responsibilities of the pharmacist as well as the titration protocol to be followed for insulin adjustments. Pharmacist educators should also be prepared to provide support to their patients after-hours, on holidays, and on weekends.

Conclusion

Because of the time commitment and complexities of CSII, practitioners may not feel comfortable prescribing it. This barrier can be overcome by collaborating with a pharmacist educator who is trained and knowledgeable regarding CSII, allowing the patient to receive more intense initial education and management. Successful implementation of CSII hinges on 2 main components—a motivated patient with developed self-management skills and a focused program conducted by knowledgeable practitioners who can provide education, management, and support.

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DISCLOSURES

There was no outside funding of this manuscript. The authors have served as certified pump trainers and have received compensation from Animas Corporation and Medtronic. LeAnn C. Boyd has served as a consultant for and received honoraria from Animas Corporation, and Causey's Pharmacy has received revenue for pump training from Animas Corporation and Medtronic.

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