Is There a Place for Insulin Pump Therapy in Your Practice?

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New insulin preparations and advances in insulin infusion technology now make it possible for patients with diabetes to safely achieve tight glycemic control using insulin pump therapy. As a result, there as been a significant increase in insulin pump use over the past decade. The evidence supporting the importance of insulin pump therapy and its use was reviewed in a 2002 study by Pickup and Keen,[1] who estimated that > 130,000 Americans with diabetes were using insulin pumps for daily treatment. However, manufacturers now estimate that ~ 375,000 patients in the United States use insulin pumps.

In the past, insulin pump manufacturers focused primarily on individuals with type 1 diabetes, who were seen by endocrinologists and other diabetes specialists. However, with the rapidly growing use of insulin pumps among people with type 1 diabetes, practitioners outside of these specialty areas will undoubtedly have greater exposure to this technology for their patients with type 1 diabetes. In addition, with the increasing prevalence of type 2 diabetes and growing recognition for the clinical and financial benefits of tight glycemic control in both type 1 and type 2 diabetes, combined with competitive market pressures, there is an increased focus and interest in insulin therapy in nonspecialty practices, where most patients with type 2 diabetes are now seen. Although the marketing activities of the insulin pump companies raise awareness of the benefits of insulin pump therapy, they also create the potential for confusion, inadequate training, and ineffective follow-up. Successful intervention with insulin pump therapy requires an experienced and motivated health care team.

This article provides some practical guidelines for initiating insulin pump therapy in nonspecialty practices. It is not our intention to present specific recommendations regarding insulin dosages and adjustments to therapy. Rather, our goal is to help clinicians acquire a better understanding of the knowledge and expertise they must possess to safely and effectively use insulin pump therapy with their patients.

Why Use Insulin Pump Therapy?

Insulin pump therapy improves glycemic control and reduces hypoglycemia. Findings from large randomized trials clearly demonstrate that early and aggressive management of glycemia significantly decreases the development and progression of the microvascular and macrovascular complications of diabetes.[2–6] However, improvement in glycemic control as measured by hemoglobin A_{1c} (A1C) is often associated with increased frequency of severe hypoglycemia.[2] As a result, patients' and clinicians' fear of hypoglycemia has become a significant obstacle to intensified diabetes management.[7]

Recent studies demonstrate that insulin pump therapy with rapid-acting insulin analogs not only improves glucose control, but also reduces the rate of severe hypoglycemia compared with multiple daily injection (MDI) insulin therapy.[8–16] These benefits have been reported in patients with type 1 and type 2 diabetes.

In patients with type 2 diabetes, glucose control is often difficult, despite full doses of oral agents and extremely large doses of insulin. In a recent study involving four patients with poorly controlled type 2 diabetes, Nielsen et al.[12] found that insulin pump therapy yielded a marked improvement in glucose concentrations with a corresponding decrease in A1C levels. This improvement was associated with a significant reduction in insulin dosages, suggesting that patients with type 2 diabetes that remains uncontrolled on extremely high doses of insulin may benefit from insulin pump therapy. Wainstein et al.[16] showed similar benefits in a larger study of 40 obese type 2 diabetic subjects.

A study by Raskin et al.[17] found that insulin pump therapy provided efficacy and safety comparable to MDI for type 2 diabetes but with lower eight-point blood glucose values at most time points

IN BRIEF

Insulin pump therapy is becoming a preferred treatment modality of diabetes specialists for the management of patients with diabetes. As a result, internists, general practitioners, nurse practitioners, and allied health care professionals will more frequently encounter patients using, or desiring to use, these devices. This article serves as an introduction to the principles that guide patient selection, patient education of self-management skills, and the practical aspects of pump management that everyone assisting patients on pump therapy should be aware of.

(although significance was only seen at 90 minutes after breakfast). Nevertheless, 93% of subjects said they preferred the insulin pump over MDI. Therefore, offering insulin pump therapy as an option to patients with type 2 diabetes may enhance their willingness to intensify glucose management.

What Is an Insulin Pump?

An insulin pump is a small, external device (about the size of a standard "beeper") that delivers rapid- or short-acting insulin 24 hours a day. With most systems, the pump is attached to a thin plastic tube that has a soft cannula (plastic needle) that is inserted under the skin, usually on the abdomen; however, some patients insert the device into their legs, arms, or lower back. The infusion set (cannula and tubing) must be changed every 2–3 days according to each manufacturer's instructions. The pump can be disconnected from the tubing while showering or swimming.

Insulin pumps allow users to deliver a preprogrammed basal insulin dose continuously throughout 24 hours to maintain blood glucose control between meals and overnight. Bolus doses are also given by the user before meals based on blood glucose levels, food intake (specifically the amount of carbohydrate consumed), and physical activity. A supplemental or "correction" bolus of insulin is given to treat high glucose levels.

Patients have a variety of pumps to choose from, each offering unique features. Most insulin pumps allow users to program many different basal rates to allow for variations in lifestyle and to accommodate varying insulin needs throughout the 24-hour period. Most pumps can also calculate the bolus dose based on the amount of carbohydrate consumed; the user inputs carbohydrate data. A supplemental or "correction" bolus of insulin can be calculated by the pump to treat high glucose levels. Some pumps can actually calculate bolus insulin doses once they are fed the blood glucose readings. Other features include programmable insulin-to-carbohydrate ratios, programmable correction factors, and an automatic calculation of insulin on board (the amount of insulin remaining active from the previous bolus). When properly programmed, these pumps will recommend insulin doses to the user based on current glucose level, anticipated food intake, and other factors. However, it is still up to the user to accept or override these doses and deliver the insulin. Table 1 presents a list of insulin pumps currently available.

Table 1. Currently Available Insulin Pump Systems

Company	Brand/Model	Contact
Animas	IR-1250	877-937-7867 www.animascorp.com
Deltec	Cozmo	800-826-9703 www.cozmore.com
Disetronic	Spirit	800-280-7801 www.disetronic-usa.com
Insulet	OmniPod	800-591-3455 www.myomnipod.com
Medtronic MiniMed	Paradigm	800-646-4633 www.minimed.com
Nipro	Amigo	888-651-7867 www.niprodiabetes.com

Although all insulin pumps provide the same basic functionality, each brand and model offers specific features that should be considered. Some pump brands and models offer the ability to change the shape and/or duration of the bolus (i.e., "square wave" or "dual wave") to address the meal amount and composition. A square wave bolus delivers a single insulin dose over an extended period, whereas a dual wave bolus delivers one dose of insulin immediately, and a second dose over the next few hours. Clearly, these features would be valuable for patients who are interested in using more advanced treatment strategies. Therefore, it is important to consider the value and relevance of the specific features offered with each pump. Selection criteria should also address other considerations, such as customer service and local training and support services.

Using rapid-acting insulin boluses at mealtimes with 24-hour continuous basal insulin infusion allows patients to closely mimic normal physiology. This, in turn, facilitates tighter glycemic control with less hypoglycemia.

What About the Cost?

The cost of insulin pump therapy can be an obstacle for some patients. Insulin pumps and initial supplies, including tubing, syringes, cartridges, and dressings, may cost up to $6,500. In addition, infusion sets and catheters must be purchased regularly at an annual cost of up to $2,000–3,000. Most insurance companies, including Medicare and Medicaid plans, cover the cost of insulin pump therapy for patients with type 1 diabetes after prospective approval. Reimbursement for insulin pump therapy for type 2 patients is often more difficult to obtain. In addition, patients whose plans cover only 80% of the total cost may still face substantial initial and recurrent out-of-pocket expenses. Most manufacturers provide comprehensive assistance to help patients obtain reimbursement.

What Type of Insulin Should Be Used in Insulin Pumps?

Several recent studies have shown that the rapid-acting insulin analogs aspart, lispro, and glulisine demonstrate a more physiological profile than buffered human regular insulin by mimicking mealtime and basal insulin secretion without higher risk of hypoglycemia or ketoacidosis in well-educated diabetic patients.[13,14,18–23]

There are no important observable differences among the rapid-acting analogs that are currently available. Testing of insulin stability has shown that these insulins are stable when used in insulin pumps.[24,25]

Although there has been some concern about rare incidents of blockages or clogging, there is no clear evidence that any of the insulin analogs is more or less susceptible to causing occlusions. In a randomized study that compared aspart to lispro and buffered regular when used in pump therapy, Bode et al.[26] found that clogs or blockages in pumps or infusion sets were infrequent; most subjects experienced less than one clog or blockage per 4 weeks during the 16-week trial, regardless of the insulin used. Moreover, only a small percentage of these blockages coincided with a hyperglycemic episode.

Some problems have been reported linking insulin to immunological reactions.[27] Furthermore, some patients have experienced allergic reactions to the tapes and plastics used in the infusion sets. In some instances, this can be overcome by changes in dressings or using "paint-on" skin barriers.

Who Is a Good Candidate for Pump Therapy?

Anyone with the motivation to achieve tighter glucose control and the ability to pay for this technology is a good candidate for insulin pump therapy. Patients must be willing to learn general principles of diabetes self-management and specific skills, such as carbohydrate counting and insulin correction and adjustment. In short, patients must be willing to learn advanced insulin management skills before moving to an insulin pump. Patients then must be willing and able to master insulin pump operation and adhere to their prescribed regimens. Table 2 presents key attributes of a good insulin pump candidate. Table 3 provides a checklist for knowledge and skills patients will need to be successful with pump therapy.

Table 2. Key Attributes of Good Insulin Pump Candidates

Patients must be willing and able to:

- Learn and apply basic diabetes self-management skills
- Learn and apply advanced diabetes self-management skills
- Learn to operate an insulin pump
- Follow their prescribed regimens
- Learn and apply troubleshooting skills
- Meet with their health care team as scheduled
- Pay for their insulin, insulin pump, glucose monitoring device, and all disposables (i.e., infusion sets, glucose test strips/sensors)

After patients have learned these skills, they must then be willing to follow the prescribed treatment plan. This includes a willingness to monitor blood glucose levels at least four to six times daily and to document the results. Successful insulin pump therapy also requires adherence to manufacturer instructions regarding the frequency for changing the infusion set.

Table 3. Requisite Knowledge/Skills Checklist

1. Fundamental diabetes self-management skills

The patient can:

___ Detect, prevent, and treat hypoglycemia
___ Manage sick days (hydration, medication adjustment, ketone testing, sick day plan)
___ Properly operate glucose monitoring device (test procedure, quality control, troubleshooting, storage/maintenance, documenting test results)

2. Advanced diabetes self-management skills

The patient can:

___ Count carbohydrates
___ Calculate a carbohydrate-to-insulin ratio
___ Calculate correction bolus doses
___ Use glucose monitoring results (pattern management)

3. Insulin pump operation and maintenance

The patient can:

___ Insert/attach cannula
___ Calculate, program, and administer insulin (basal, bolus, and correction doses)
___ Adhere to prescribed frequency for changing sites and infusion sets
___ Provide proper care and maintenance
___ Troubleshoot problems

It is important to inform patients about insulin pump therapy before initiating treatment to avoid misunderstandings and unrealistic expectations. Patients need to understand the strengths and limitations of pump therapy (what an insulin pump will and will not do) and the initial and ongoing costs involved. To be safe and successful, patients must also understand and agree to fulfill their responsibilities regarding initial and ongoing education and training and adherence to the prescribed regimen, including self-monitoring of blood glucose levels, changing of infusion sets, follow-up contact, visits with the health care team, and all other aspects of the treatment plan.

When working with adolescent patients, many clinicians have found it valuable to use behavioral contracts that provide a detailed list of responsibilities the patient agrees to fulfill. Figure 1 presents a sample contract.

Important considerations. Patient self-care behaviors are rarely constant; this is particularly true with adolescents. An early study by Klingensmith et al.[15] found that adolescent subjects (ages 9–17 years) often experienced problems with peer acceptance of pumps, had difficulty with infusion set insertion and skin care, were unable to perform home blood glucose monitoring consistently, and made inappropriate manipulations of insulin dosage. However, a more recent study by Boland et al.[9] reported that adolescents using insulin pumps found coping with diabetes to be less difficult than adolescents using MDI regimens. The researchers concluded that insulin pump therapy provides an effective means to lower A1C levels and reduce the risk of hypoglycemia without adversely affecting psychosocial outcomes in adolescents with type 1 diabetes.[9]

In short, adherence to prescribed insulin pump therapy, particularly in adolescents, is a complicated challenge with multiple issues. However, proper identification of problems and appropriate intervention can result in reestablishment of good glycemic control. In our own practices, we have observed that it takes an average of 6 months before patients feel comfortable with their pump therapy. Frequent contact with the health care team usually shortens this time frame.

Who is a Good Candidate for Prescribing Pump Therapy?

Insulin pump therapy is not as complicated as many believe. However, clinicians must possess the necessary knowledge, skills, and resources to safely initiate insulin pump therapy and provide diligent follow-up care to patients. To be successful, clinicians must be well grounded in the principles and strategies of diabetes management and basic insulin pump therapy. (See Table 3.) Moreover, they must take the time to learn basic and advanced strategies involved with insulin pump operation and use. In other words, clinicians must learn and master everything their patients need to know about pump therapy, and they must be able to provide expert advice regarding pattern management,

PATIENT INSULIN PUMP THERAPY CONTRACT

I (patient name) agree to:

1. give a meal bolus for all meals and snacks.
2. correct all high blood glucose readings above _____ down to _____.
3. check ketones every time my blood glucose is > 300 mg/dl.
4. follow sick day rules as directed.
5. monitor my blood glucose daily as prescribed.
6. review my bolus and blood glucose history at least once per week.
7. change my insulin and catheter site every 2–3 days or sooner if needed.
8. call my diabetes team for assistance if my blood glucose levels are out of target range consistently for > 3–4 days.
9. attend advanced diabetes class within 6–12 months from my pump start date.

I (patient name) understand that if any of the above is not being done, my physician can discontinue insulin pump therapy as he/she deems appropriate.

Patient Signature: _____ Date: _____

Diabetes Educator: _____ Date: _____

Figure 1. Sample Patient Contract

dosage adjustments, and troubleshooting.

Most busy practices have difficulty accommodating the lengthy patient visits required to provide necessary education and training in basic and advanced diabetes education skills, insulin pump operations, and troubleshooting. Therefore, clinicians who want to use insulin therapy in their practices must have access to qualified individuals who can provide initial education and training in all aspects of pump therapy and ongoing education and follow-up support to patients on a long-term basis. Establishing a team of qualified and experienced health care providers is a prerequisite component of insulin pump use.

Reliance on a health care team should not be confused with simply using the training services provided by manufacturers. Although many insulin pump manufacturers employ consultants or "trainers" to provide initial training to patients and caregivers, this service does not cover all of the basic education needed for successful insulin pump use, nor does it provide adequate follow-up to address the clinical and psychosocial issues inherent to all diabetes management regimens.

Another essential component is having after-hours coverage by an experienced clinician. Most of the major pump manufacturers provide 24-hour technical support; however, these services are generally limited to handling mechanical problems with the pumps themselves. They are not intended to provide acute patient care. Therefore, clinicians must ensure that qualified individuals will always be available to provide medical care and assistance to patients on pump therapy.

As discussed earlier, studies have shown insulin pump therapy to be beneficial in treating both type 1 and type 2 diabetes. This clearly creates an opportunity for many primary care physicians to incorporate insulin pump therapy into their diabetes management strategies. However, a pediatric diabetes specialist should treat all children with type 1 diabetes up to age 18 years.

How Can Patients Get Started?

Insulin pump training is analogous to diabetes self-management education in that it has three defined stages: *1*) pre-pump preparation and start-up training (survival skills); *2*) advanced pump training (lifestyle self-management); and *3*) maintenance and expansion of competencies (continuing education). This article focuses on the first stage, pre-pump preparation and start-up training, because it is crucial to patients' long-term success with pump therapy.

Pre-pump preparation. A crucial component of pre-pump preparation is ensuring that patients receive comprehensive education and training in the fundamentals of diabetes self-management. Without a solid understanding of basic self-management skills, initiating insulin pump therapy is neither safe nor effective. Once a patient can demonstrate proficiency in basic self-management skills, the next step is to start the patient on a basal-bolus insulin regimen with frequent blood glucose monitoring. This is where advanced management skills (i.e., carbohydrate counting, understanding insulin-to-carbohydrate ratios, and calculating correction doses) come into play; patients must be fully competent in these skills. The checklist provided in Table 3 can be used to make this assessment. It will also be necessary to assess the need for a new or modified meal plan; between-meal and bedtime snacks are not required with basal-bolus therapy or insulin pump therapy.

Start-up training. Assuming a patient has mastered basal-bolus therapy using a syringe and/or insulin pen, the next step is insulin pump training. Patients must be able to demonstrate proficiency in all aspects of pump operation. Working with patients and health care teams, pump manufacturers' local "pump trainers" can provide valuable assistance in helping patients learn to use and get started with their insulin pumps.

Once patients have completed their education and training, they are ready to begin pump therapy. Many diabetes experts have patients complete 2

Table 4. Troubleshooting Checklist

1. **Before you do anything:**
   - Check your glucose. Also check your ketones if your glucose is > 300 mg/dl.
   - Inject a correction bolus as needed. Your correction bolus dose is _____.
   - Call for assistance if you have any questions or problems:
     Emergency phone number
     _____

2. **Troubleshoot your pump and infusion set after your glucose is under control.**

   Tubing
   - Is the tubing kinked, disconnected, or loose?

   Air
   - Is there air in the system?
   - Did you prime after changing the cannula site?

   Site
   - Are you regularly changing the cannula and infusion set?
   - How long has it been since the last site change?
   - Is there leakage at the site?
   - Is the site red, painful, or itchy?
   - Do you smell insulin?

   Batteries
   - Are the batteries depleted?

   Reservoir
   - Is the pump properly reset before insertion?
   - Is there an adequate amount of insulin?

   Settings
   - Are the time and A.M./P.M. setting correct?
   - Has the basal rate been set properly?

   Bolus
   - Is the bolus taken before snacks and meals?
   - Are the carbohydrates and dosages calculated correctly?
   - Is the correction factor calculated correctly?
   - Do the calculated dosages adequately accommodate your activity level?

   Insulin
   - Is the insulin past expiration?
   - Has the insulin gotten warm or been frozen?

consecutive days of training to get familiar with their pumps and work through any issues they may be having. Patients will then come back 3 days later, giving the clinician an opportunity to answer questions and assess competency. Depending on the situation, clinicians may ask patients to return in 2 weeks, 6 weeks, and then 3 months for follow-up. During this stage, patients will be asked to monitor their blood glucose six to eight times per day. As a safeguard, clinicians should be prepared to collect these data as often as daily or as infrequently as every week until patients' glucose levels are stable and controlled.

It is also important to provide patients with phone numbers for emergencies. Although many insulin pump manufacturers will provide limited phone support by the pump trainer, patients must also have emergency access to their health care team.

After patients become competent and comfortable with their insulin pumps, clinicians should then move them to more advanced pump therapy, such as using custom bolusing, alternate basal rate profiling, and temporary rates.

What Happens If Something Goes Wrong?

The insulin pump itself is rarely the problem when insulin infusion is interrupted. Usually the problem is the result of a patient inadvertently pulling out the catheter, disconnecting the tubing, or not changing the infusion set or site as prescribed. However, pump malfunction should not be dismissed outright; the problem may be because of depleted batteries or electrical/mechanical malfunction. Patients should always follow up on error codes by calling the manufacturer's toll-free number for assistance. Table 4 presents a troubleshooting checklist that patients and clinicians can use to identify and solve problems.

Metabolic correction during pump failure. Although pump problems are rare, patients should always be prepared to handle a disruption in insulin infusion. Patients should always carry:

- An insulin pen or vial/syringe
- An infusion set and reservoir if traveling; patients should also store these supplies in commonly visited places
- Glucose and ketone testing supplies
- A source of rapid-acting carbohydrate

Regardless of the cause of the problem, patients should get glucose levels under control before attempting to troubleshoot the pump or infusion set. Patients should immediately check blood glucose levels. If glucose is elevated, they should inject a correction bolus of insulin using a syringe or pen before restarting the pump. Patients should also test for ketones if blood glucose is > 300 mg/dl. All patients should know their correction dose before initiating insulin pump therapy. Table 5 presents a formula for calculating a correction dose.

Summary

Tight glucose control has been shown to reduce both microvascular and macrovascular complications in type 1 and type 2 diabetes. Insulin pump therapy has been shown to be safe and effective in helping patients achieve good glycemic control. However, successful insulin pump therapy is dependent on each patient's ability and motivation to learn to use insulin pumps correctly; comprehensive initial and ongoing education delivered by qualified clinicians is the key. In addition, patients must have strong, ongoing support from an experienced health care team as they learn to use more advanced insulin pump strategies. Insulin pump therapy is not as complicated as many believe; however, clinicians must be will-

Table 5. Calculating a Correction Dose

The formula for calculating a correction dose is as follows:

1. Add the total daily dose (include both basal and bolus amounts) and then divide 1,800 by that number. The result is the decrease in glucose (mg/dl) one would achieve with 1 unit of insulin as a correction dose.

   1,800/Total Insulin Dose = Decrease in Glucose (mg/dl) per 1 unit of insulin
   (This is the "insulin sensitivity factor.")

2. Calculate the number of units of insulin needed based on the current glucose level and planned carbohydrate intake. Patients should test their glucose levels 2–3 hours after delivering the bolus to assess the outcome.

   Example: J.D. normally takes 30 units of insulin per day: 15 units as basal and 15 units as bolus (5 units with each meal)

   1,800/30 = **60** (insulin sensitivity factor)

   A correction dose of 1 unit of insulin would be expected to decrease the blood glucose by 60 mg/dl. Patients should be taught to use their insulin sensitivity factor (this can be modified to ± 25%), as follows:

   Blood Glucose – Target/Sensitivity = Correction Dose

   If the premeal glucose is 198 mg/dl (~ 90 mg/dl above the premeal target of 110 mg/dl), the patient would need to add 1.5 units of insulin to the bolus insulin dose.

   (198 – 110)/60 = **1.5 units**

   J.D. would then add 1.5 units to his meal bolus dose to lower his glucose into his target range.

   It is important to note that this is just a starting point that must be assessed with follow-up blood glucose readings after the correction bolus is given.

ing to acquire the knowledge and training necessary to safely and effectively use this important tool to manage diabetes in nonspecialty practices.

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Note of disclosure: *Dr. Skyler serves on a speakers bureau for Novo Nordisk and Sanofi-Aventis; sits on advisory panels for Animas, Patton Medical, Sanofi-Aventis, Smiths Medical, and Valeritas; is a stock shareholder in Animas, Medingo, and Patton Medical; and has received consulting fees from Eli Lilly, Medingo, Novo Nordisk, Roche Diagnostics, Sanofi-Aventis, Smiths Medical, and Valeritas. These companies manufacture insulin pumps, insulin products that can be used in pump therapy, and/or other insulin delivery systems. Dr. Ponder has received honoraria for speaking engagements from Animas, which manufactures insulin pumps. Ms. Kruger has received honoraria from Novo Nordisk, Eli Lilly, and Sanofi-Aventis, all companies that manufacture insulin products that can be used in pump therapy. Ms. Matheson has received honoraria or consulting fees from Animas and Medtronic MiniMed, both of which manufacture insulin pumps. Mr. Parkin has received consulting fees from Abbott Diabetes Care, Eli Lilly, Sanofi-Aventis, and Smiths Medical, all of which manufacture insulin pumps or insulin products that can be used in pump therapy.*