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Insulin Pumps: Beyond Basal-Bolus


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EDUCATIONAL OBJECTIVE: Readers will consider which patients might be good candidates for an insulin pump

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Insulin pumps: Beyond basal-bolus

ABSTRACT

Insulin pumps are a major advance in diabetes management, making insulin dosing easier and more accurate and providing great flexibility, safety, and efficacy for people who need basal-bolus insulin therapy. They are the preferred treatment for people with type 1 diabetes and many with type 2 diabetes who require insulin. This article reviews the basics of how insulin pumps work, who benefits from a pump, and how to manage inpatients and outpatients on insulin pumps.

KEY POINTS

Insulin pumps allow for more accurate insulin dosing than multiple daily injections, resulting in less drastic extremes in blood sugar.

Insulin pumps allow for more individualized basal insulin coverage than long-acting injectable insulin.

Both the patient and provider need a good understanding of insulin pump therapy for successful pump management.

THE ADVENT OF the insulin pump in the late 1970s was a step forward in diabetes treatment,¹ and recent improvements make these devices easier to use in intensive insulin management. Today, more than 400,000 people in the United States are thought to be using an insulin pump.²

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With a pump, patients can adjust the dosage and discreetly give themselves boluses by simply pushing a button instead of giving themselves multiple daily injections. Also, pump therapy can be tailored to correct for hepatic glucose production in a way that injections cannot.

This article reviews the clinical application of continuous subcutaneous insulin therapy—ie, the insulin pump—and provides recommendations for patient selection and management.

■ INDICATIONS FOR AN INSULIN PUMP

The American Association of Clinical Endocrinologists³ recommends considering an insulin pump for patients with type 1 or 2 diabetes mellitus who have a clear indication:

- Suboptimal control on basal-bolus injections, ie, not achieving glycemic goals despite maximal adherence to multiple daily injections
- Wide and erratic glycemic excursions
- Frequent severe hypoglycemia, or hypoglycemia unawareness
- A marked “dawn phenomenon” (spike in blood glucose level early in the morning)
- Pregnancy or planning for pregnancy
- Erratic lifestyle
- Personal preference.

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TABLE 1

Who is a good candidate for an insulin pump?

Patients with type 1 diabetes who:

- Self-monitor blood glucose four times per day
- Take injections more than three times a day
- Have completed diabetes education and carbohydrate-counting training
- Have evidence of autoimmunity (positive for islet-cell antibodies or glutamic acid decarboxylase antibodies)
- Have low C-peptide with normal to high glucose levels

Patients with gestational diabetes who:

- Self-monitor blood glucose and are on multiple daily injections

Patients with type 2 diabetes who:

- Meet the same multiple-daily injection and self-monitoring requirements as for type 1 diabetes
- Have evidence of beta-cell failure with low C-peptide

WHO IS A GOOD CANDIDATE FOR AN INSULIN PUMP?

Good candidates for a pump are patients with type 1 diabetes (and some with type 2) who are well versed in taking multiple daily injections, are already checking their glucose four or more times daily, “counting carbs” (estimating or, preferably, measuring how much carbohydrate they are eating, and limiting their intake accordingly), and demonstrate the ability to adjust their dosing appropriately (Table 1).

A pump is not a shortcut to checking glucose less frequently or making fewer decisions. However, for those who actively manage their diabetes, it provides more real-time flexibility and some important safety features, as discussed below.

IS A PUMP BETTER THAN INJECTIONS?

Several studies have compared insulin pump therapy and multiple daily injections.⁴⁻⁷ While some found no difference in glucose control in terms of hemoglobin A_{1c} or hypoglycemia, others showed improved glucose control with pumps in patients who had higher baseline hemoglobin A_{1c} levels (> 10%).⁶ In this subgroup, a pump lowered hemoglobin A_{1c} an additional estimated 0.65% compared with multiple daily injections.⁶ Fructosamine levels also improved in pump users.⁶

Using continuous glucose monitoring for 3 days in a study in children with type 1 diabetes, Schreiver et al⁸ found lower insulin

requirements and less-severe glycemic excursions with a pump than with multiple daily injections.

A 2013 study⁹ of 57 patients ages 13 to 71 with type 2 diabetes who were struggling to control their blood sugar with multiple daily injections found that they achieved better control with less insulin using a pump.

A meta-analysis found pump therapy to be more effective than multiple daily injections for those who used it more than 1 year.¹⁰

ADVANTAGES AND DISADVANTAGES OF INSULIN PUMP THERAPY

Intensive glucose control reduces microvascular complications in type 1 diabetes.¹¹⁻¹⁴ The advantages of using a pump include better adherence, more accurate dosing, greater lifestyle flexibility, control of the dawn phenomenon without induction of nocturnal hypoglycemia, and the ability to suspend or temporarily reduce basal insulin to compensate for increased physical activity.¹⁵

Disadvantages include the high degree of technical aptitude required, the need for high-level engagement, skin reactions to tape, a higher risk of diabetic ketoacidosis from pump malfunction, infusion-site problems such as “tunneling” of insulin (leakage of insulin along the outside of the cannula and back to the skin surface) and clogging of the infusion set, and a risk of inactivation of insulin from exposure to heat, which can lead to ketoacidosis in a few hours if not addressed promptly.¹⁵

IS IT COST-EFFECTIVE?

There is evidence that continuous subcutaneous insulin infusion is cost-effective, both in general and compared with multiple daily injections for children and adults with type 1 diabetes mellitus. Cohen and Shaw¹⁶ found that life expectancy and quality-adjusted life-years increased in pump users, although the price per life-year gained varied greatly depending on the model used.

And this therapy is expensive. Most pumps cost more than \$6,000, and supplies cost about \$300 per month. Most insurance providers cover this therapy for patients with type 1 diabetes (Table 2) but less often for those with type 2. Further, many insurance policies have

A pump is not a shortcut to checking glucose less frequently, or to making fewer decisions

copayments, and patients may find a 20% copayment a significant financial burden. Physicians need to obtain preapproval for insulin pumps from the insurance company. Typically, prescriptions for supplies are written annually. Despite these significant costs, most patients with type 1 diabetes who use an insulin pump find that the benefits of improved control and greater independence justify the cost.

An annual review of currently available insulin pumps and other diabetes-related equipment is published in *Diabetes Forecast*.¹⁷

■ PATIENT PERSPECTIVE ON INSULIN PUMP USE

Many patients who use a pump find that it gives them greater flexibility to adjust to day-to-day changes in schedules and routines. For example, consuming an extra serving at a meal could necessitate another injection for a patient on multiple daily injections, but a pump user would need only to push a few buttons. With cell phone apps available to control some pumps, many people find that an insulin pump is more discreet and easier to manage than carrying around injection supplies. Further, the complex calculations of carbohydrate ratios and correction factors are easier and more accurate with a pump.

In an open-label randomized study,¹⁸ 29 of 41 patients with type 1 diabetes said they preferred a pump to multiple daily injections.

Conversely, some people do not want a pump because it is attached all the time and identifies them to others as having an illness. Other patients do not trust a machine and want control in their own hands. (Actually, machines typically are much more reliable and less mistake-prone than humans.)

■ HOW DOES A PUMP WORK COMPARED WITH MULTIPLE DAILY INJECTIONS?

Patients taking multiple daily injections must use two types of insulin: a long-acting one that reaches a steady level in the blood without a peak and lasts from 12 to 24 hours, and a rapid-acting one taken with meals, usually having a peak of action and an effect lasting 3 to 5 hours. The idea is to approximate normal insulin patterns, with a basal level in the background and peaks (boluses) of insulin

TABLE 2

Centers for Medicare and Medicaid Services reimbursement requirements for insulin pumps

The patient has completed a comprehensive diabetes education program and has been receiving multiple daily injections of insulin with frequent self-adjustments for at least 6 months before pump initiation.

The patient has documented self-monitoring of blood glucose frequency an average of at least four times per day during the previous 2 months.

The patient must also meet at least one of the following criteria:

- Hemoglobin A_{1c} > 7.0%
- History of recurrent hypoglycemia
- Wide fluctuations in blood glucose before mealtime
- Dawn phenomenon with fasting plasma glucose frequently > 200 mg/dL, or a history of severe glycemic excursions
- Patient on pump therapy before enrollment and has documented self-monitoring of blood glucose an average of at least four times per day during the month before enrollment.
- Fasting C-peptide ≤ 110% of the lower limit of normal or ≤ 200% of the lower limit of normal if creatinine clearance is ≤ 50 mL/min with concurrent fasting plasma glucose ≤ 225 mg/dL
- Beta-cell autoantibody-positive (islet-cell antibodies or glutamic acid decarboxylase antibodies)

Centers for Medicare & Medicaid Services. <https://www.cms.gov/manuals/iom/list.asp>.

with carbohydrate intake.

Insulin pumps use only one kind of insulin—a rapid-acting one, ie, lispro, aspart, or glulisine. They preserve the basal-bolus concept, but with many refinements (discussed below).¹⁵

Most pumps are attached to the patient by plastic tubing that connects the reservoir to a subcutaneous cannula or steel needle. However, some pumps have a reservoir directly attached to a subcutaneous cannula without the tubing. This type of pump is controlled with a remote device.

The infusion set (cannula or needle and tubing) and the site should be changed every third day to minimize the risk of infection and abnormal delivery due to protein buildup on the cannula os, epithelial healing, and irritation around the site. Failure to do so often results in higher blood glucose concentrations.¹⁹

The patient and healthcare team work to-

gether to calculate the patient's daily insulin needs, and the pump is programmed based on the patient's requirements, lifestyle, and sensitivity to insulin. Once the pump is started, the patient operates it to deliver the insulin dose according to carbohydrate intake and blood glucose level.

■ PUMP SETTINGS

Basal rate

The basal rate is programmed by the physician and is intended to mimic physiologic insulin release. The pump can be set to a number of basal rates within any 24-hour period. This provides more physiologic matching of insulin delivery to hourly insulin needs based on the patient's daily schedule.

If the patient has been taking multiple daily injections, the hourly basal rate can be calculated by dividing the daily basal dose by 24. However, lower rates are usually used after midnight, and rates are increased early in the morning to counteract the dawn phenomenon.

The rates can also be adjusted temporarily (for up to 24 hours), with a feature called the *temporary basal rate*. People tend to have higher blood glucose levels when they have a respiratory illness, are under significant stress, or are menstruating. Thus, a person with influenza could increase the basal rate by 25%, or a student could run a temporary basal rate of 150% for 4 hours before taking a final exam.

Conversely, exercising increases insulin's effectiveness at the muscle level, and insulin requirements drop. To counteract this, one would temporarily decrease the basal rate in the pump before exercising.

Many factors affect the bolus dose

A bolus of insulin is given for meals and to correct hyperglycemia, as with multiple daily injections. A pump calculates the bolus based on the carbohydrate ratio, correction factor, or both. These ratios are programmed into the pump by the physician. A benefit of the insulin pump is that the patient just has to input the amount of carbohydrates to be eaten or record a blood glucose level and the pump will calculate the bolus dose of insulin to be given.

The carbohydrate ratio is the amount of insulin that should be taken per amount of carbohydrate. A typical ratio is 1:15, meaning

that the patient should take 1 unit of insulin for every 15 g of carbohydrates to be eaten. This varies by patient depending on insulin sensitivity.

The correction factor describes how much the glucose level is expected to drop per unit of insulin given. For example, if the target glucose level is 100 mg/dL and the correction factor is 25, then the patient will get 1 unit of correction of insulin if his or her glucose level is 125 mg/dL, 2 units if it is 150 mg/dL, and so on. A pump can dispense fractions of a unit.

The target glucose level or range is set by the physician and patient and is one of the factors the pump uses in calculating a bolus dose. Insulin pumps allow for multiple target glucose levels. Commonly, to minimize the risk of hypoglycemia, a higher (less strict) target is set for bedtime and overnight than for daytime.

Active insulin time defines how soon the patient can take another bolus.

Often, people eat more than they thought they would. They may also find that the glucose level did not increase or decrease as much as expected. Many patients who actively manage their glucose take additional boluses of insulin after a meal if their glucose is higher than they thought it would be. A patient taking injections cannot know how much of the insulin from the before-meal bolus is still working and has to guess.

Insulin pumps use a logarithmic formula to calculate this and prevent the user from "stacking" insulin boluses and lowering the glucose level too much. For example, if the active insulin time is 4 hours and the patient took a bolus for lunch at noon, he or she would be unable to take a full insulin correction dose until 4:00 PM. The patient can override this feature. Although the active insulin time varies from patient to patient, it is rarely more than 4 hours.

Additional safety features

Suspend. When a person who is taking insulin injections starts to experience hypoglycemia, he or she has one option—to eat something to treat the low blood glucose. The insulin injection has already been taken and cannot be reversed. However, with an insulin pump the patient can first suspend the pump so that

Most insulin pumps cost more than \$6,000, plus about \$300 per month for supplies

no additional insulin is infused until it is safe again, and then eat to treat the low sugar level. This allows the patient to eat less, prevent overtreatment, and, hopefully, prevent rebound hyperglycemia.

Reverse correction. When patients take insulin for an upcoming meal, they estimate the amount needed for the carbohydrates that they are about to eat as well as how much correction is needed. If their glucose level is below the target range, they may or may not subtract insulin from the dose to achieve the glucose target. The pump does this automatically, resulting in a lower dose of insulin for that bolus. This allows the patient to take a bolus for a meal even if he or she is below the target, and thus prevent hyperglycemia.

■ CAN INSULIN PUMPS BE USED IN THE HOSPITAL?

Patients can keep using their insulin pump in the hospital under the right conditions.

Inpatient hypoglycemia increases the risk of death, and although not all patients require tight glycemic control, there is still benefit in avoiding extremes in blood sugar levels,²⁰ including at night.²⁰⁻²² Insulin pump therapy, when used in the hospital, results in fewer episodes of severe hyperglycemia (glucose levels > 300 mg/dL) and hypoglycemia (levels < 40 mg/dL) than multiple daily injections.²² Moreover, most pump users feel more comfortable when they can manage their own therapy. Using the pump in the hospital has the additional benefit that patients can treat themselves before and after meals easily with less staff time and effort.

Bailon et al²³ retrospectively studied 35 patients with insulin pumps in 50 hospitalizations. More than half of the patients were allowed to continue using their pump in the hospital. Reasons for discontinuing the pump included lack of access to supplies, unfamiliarity with the pump, attempted suicide, malfunctioning hardware, diabetic ketoacidosis, and altered mental status. Patients using their pump had fewer episodes of hypoglycemia (glucose levels < 70 mg/dL) than patients who removed their pump. In patients who continued using the pump throughout their hospitalization, no adverse events (eg, site infection or

mechanical failure) were noted.

Leonhardi et al²⁴ reviewed 25 hospital admissions, and the outcomes were similar to those reported by Bailon et al,²³ with no adverse outcomes related to the pumps.

When using an insulin pump in the hospital

When a physician wants a patient to continue using an insulin pump in the hospital, a number of things must happen. The nursing staff must be informed that the patient is wearing a pump and can self-administer insulin. Most facilities will still follow routine protocols for checking blood glucose but will document that the patient is administering his or her own insulin. The patient must be well enough to manage the pump. If the infusion site needs to be changed, the patient would be expected to do so with his or her own supplies.

Imaging and insulin pumps

Advice differs on what to do if a patient with an insulin pump needs to undergo radiographic imaging. For example, the University of Wisconsin radiology department says it is safe to keep an insulin pump in place if the x-ray beam will be on for less than 3 seconds at a time and if the device is covered by a lead apron.²⁵ However, radiation can induce electrical currents in the circuitry, which can alter the function of the pump. For this reason, some manufacturers recommend removing the device before the patient enters any room in which radiation or magnetic resonance imaging will be used.²⁶⁻³¹

Insulin pumps and surgery

Insulin pumps have been used in the perioperative and intraoperative periods, with positive outcomes.³² An analysis of 20 patients on pumps undergoing a total of 23 surgeries (mostly orthopedic procedures) found that 13 of the 20 patients wore their pump during surgery. No adverse events were noted in any of these cases, although the sample size was small.³³

Corney et al³⁴ retrospectively compared insulin pumps with alternative methods of perioperative glucose management. Multiple surgical specialties were included. No significant difference in mean blood glucose levels was found between those who continued to use their pump and those who used other methods. In those who continued to use their

Insulin pumps preserve the basal-bolus concept, but with refinements

pump, there were no episodes of intraoperative technical difficulties related to the pump.

Any patient who may be undergoing a procedure or surgery must let the surgeon and anesthesiologist know that he or she has a pump. If the infusion site is too close to the site of the surgery or procedure, it must be moved.

Concerns during surgery include catheter or site disconnection or loss, crystallization within the tubing (a potential problem not limited to surgery), and pump malfunction. If the procedure involves imaging, the pump should probably be disconnected or covered by lead shielding as directed in the pump manufacturer's manual. The surgeon and anesthesiologist must decide whether to continue use of a pump during a surgical procedure. However, the study by Corney et al³⁴ shows it is possible.

Most office-based procedures can be done with the insulin pump in place, as the patient is not under general anesthesia and so can adjust the insulin regimen as needed.

Abdelmalak et al,³⁵ in a comprehensive review of insulin pump use in noncardiac surgery, commented that the type of surgery may play a role in determining the best approach to perioperative glucose management. Major surgery causes a large inflammatory response that makes it difficult to control blood sugar, especially when steroids or beta agonists are given, whereas minor surgery does not affect blood glucose nearly as much. The authors offered recommendations on pump use during various surgical procedures depending on the length of the procedure:

- If surgery is anticipated to last less than 1 hour, then keep the insulin pump on, and have the patient manage corrections preoperatively and postoperatively.
- For surgery of intermediate length (1–3 hours), have the patient take a bolus of 1 hour's worth of insulin (based on the basal rate for that time period) before the procedure, then remove the insulin pump. Do this only if blood sugar is normal or close to normal. If the patient is severely hyperglycemic, remove the insulin pump and start an intravenous insulin infusion.
- If the procedure will take more than 3 hours, remove the pump and start an insulin infusion regardless of the blood sugar level.³⁵

■ AIR TRAVEL AND INSULIN PUMPS

Insulin pumps can be easy to manage during airline travel if the user is prepared (Table 3).

First, it is important to have a letter from the treating physician stating that the pump is a necessary medical device. All supplies should be carried on and in a separate bag for easy inspection. The more forthcoming the user is at the security checkpoint, the easier the process.

According to the Transportation Security Administration, insulin pump users can keep their pump on during screening, and the metal detectors and full-body scanners will not harm the device.³⁶

However, manufacturer recommendations differ. Medtronic recommends that patients not expose their insulin pump to x-rays, and that instead of going through a full-body scanner the patient should request a pat-down.³⁷ Animas recommends the same.³⁸ OmniPod states that their system can be worn through airport imaging, making it the only approved continuous insulin delivery system that can be taken through airport imaging.³⁹

Another potential problem is the change in atmospheric pressure during takeoff and landing. Bubbles can form in the insulin reservoir as air pressure decreases with ascent, thereby displacing insulin from the pump to the patient. The opposite happens during descent. King et al⁴⁰ corroborated this phenomenon with Animas and Medtronic pumps. Asante recommends removing their pump tubing during takeoff and landing.³⁰

■ IF PROBLEMS ARISE

Like any machine, an insulin pump can fail. Most failures result in lack of insulin delivery—the patient does not get excess insulin from insulin pump failure. Excess insulin delivery is most often due to operator error. All insulin is either preprogrammed (basal by provider or patient) or must be confirmed by the patient at the time of delivery (meal or correction boluses).

Pump manufacturers have 24-hour support programs and hotlines, with experts who will either walk the patient through the problem or send a replacement pump—often within 24 hours.

The infusion set and the site should be changed every 3 days

EVOLVING TECHNOLOGY

Pump technology is evolving quickly. On the way are “smart” pumps that interact with other systems, smaller pumps with advanced touch-screen features, and patch pumps that do not have tubing but operate similarly to pumps with tubing (ie, a cannula is still required for insulin delivery).

Some insulin pumps can be linked to an external glucose sensor. These systems provide a great amount of information to the patient and provider. Often, there is increased awareness of fluctuations in glucose, allowing earlier intervention to prevent high and low glucose excursions. Sensor-augmented pumps may further improve safety by suspending infusion during hypoglycemia.^{41,42}

Researchers continue to strive for closed-loop systems that would allow the pump to automatically respond to circulating glucose and thus provide truly physiologic control.⁴³ A recent study showed the effectiveness of the outpatient use of a bihormonal (insulin and glucagon) “bionic pancreas,” which provided

TABLE 3

Recommendations for patients with an insulin pump who plan air travel

- Bring a note from your physician stating you have diabetes mellitus and are carrying insulin supplies.
- Always bring extra supplies (pump supplies, syringes, test strips, lancets, and an extra insulin bottle). Once opened, a bottle of insulin can be kept at room temperature for 28 to 42 days. Those that are unopened should be refrigerated.
- Notify the Transportation Security Administration (TSA) staff that you wear an insulin pump and have diabetic supplies before sending your belongings through the x-ray machine. If you carry a pump with tubing, you can detach the device and send it through the x-ray machine. TSA staff will swab your hands after you touch the pump to test for explosive material, which is standard procedure.
- If you are concerned about insulin dosing during takeoff and landing, you can detach your pump at these times. Make sure to prime the tubing again before reattaching it to ensure the tubing is free of air.

improved glucose control and similar or less hypoglycemia in adults and adolescents who had been using a traditional insulin pump.⁴⁴ ■

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