Insulin Patch Pumps

A New Tool for Type 2

Type 2 diabetes is the most common type of diabetes in the world, accounting for 90% to 95% of all cases. When first diagnosed, Type 2 diabetes is typically treated with lifestyle changes, such as increased physical activity and improved diet, and the oral drug metformin. If these measures don't lower blood glucose levels enough, other drugs are usually added. While insulin is rarely the first drug prescribed for a person with Type 2 diabetes, many people eventually require it to get the best blood glucose control possible.

Despite the promise of better control, however, many people are reluctant to start using insulin. Fear – of weight gain, low blood glucose (hypoglycemia), injection pain, and/or handling needles – is often at the root of this reluctance. Some other common barriers include feeling embarrassed about injecting insulin in public and feeling that one has failed at controlling the disease if insulin is necessary.

Even when people with Type 2 diabetes agree to take insulin, many regularly skip some doses. The most common reasons reported for skipping injections are a busy lifestyle, travel, skipped meals, stress or emotional problems, and embarrassment.

Working with an understanding health-care provider and/or diabetes educator can be a big help in overcoming many of the barriers to starting insulin and using it successfully. It can also help to carefully choose which insulin delivery device to use. For example, for many people, using insulin pens is easier than using syringes and vials. A fairly new option on the market, the insulin patch pump, may also work well for many people with Type 2 diabetes.
Traditional insulin pumps are highly technical and have complex features for adjusting basal rates and bolus doses of insulin. Such features require significant patient education and are unnecessary for many people with Type 2 diabetes. Also, the majority of people with Type 2 diabetes see a primary-care provider for their diabetes care, and very few of these providers have the level of training, time, or staff required to provide the support and education needed for successful use of an insulin pump.
The newer patch pumps, in contrast, are less technical, so while they may offer fewer insulin delivery options, they should be easier to learn to use. Patch pumps are also different from traditional pumps in that they adhere directly to the skin, so there's no tubing, and the patch itself is kept on for 24 hours, then discarded.

How it works

There are two patch pumps currently available in the United States. The OmniPod Insulin Management System, manufactured by Insulet, was the first to be marketed. But while it delivers insulin directly from a patch, with no tubing, in other respects it is much like a traditional insulin pump in that it can be programmed for individualized basal rates, has a bolus calculator, stores insulin delivery data, etc. The OmniPod was designed primarily for use by people with Type 1 diabetes,

although it can be used for treating Type 2 diabetes as well. But again, many people with Type 2 diabetes don't need all of these options and features.

In 2010 the US Food and Drug Administration (FDA) cleared Valeritas's V-Go, designed for adults with Type 2 diabetes who require insulin. It has been marketed in the United States since 2012. The V-Go is a disposable insulin delivery device that delivers a continuous, subcutaneous infusion of rapid-acting insulin. It sticks directly to the skin with a strong adhesive, allowing it to stick to the skin for 24 hours even when wet. The device is 2.4 inches long, 1.3 inches wide, and half an inch thick and weighs between 0.7 and 1.8 ounces. It is prescribed as V-Go 20, V-Go 30, or V-Go 40, along with a prescription for vials of rapid-acting insulin – either insulin aspart (NovoLog) or insulin lispro (Humalog). For people using V-Go 20, 2 vials of insulin will be needed, and for V-Go 30 or 40, 3 vials will be needed.

The numbers 20, 30, and 40 refer to the amount of insulin that is delivered at a continuous, preset basal insulin rate over a 24-hour period. All three devices allow for a total of 36 units of bolus insulin in 24 hours. For example, the V-Go 30 delivers 30 units of rapid-acting insulin continuously over 24 hours (1.25 units/hour) and on-demand bolus dosing of insulin in 2-unit increments, up to 36 units over 24 hours. In general, people starting insulin therapy with V-Go will require less insulin than they did when using an insulin pen or syringe.

There are four buttons on the V-Go. The "needle button" inserts the needle into the skin after the device is attached to the body (meaning the user never has to see it). The "needle release button" retracts the needle back into the V-Go so the device can be removed. The "bolus ready button," when pressed, releases the "bolus delivery button," which is used to deliver bolus doses of insulin. The "bolus ready button" and "bolus delivery button" must both be pressed every time a 2-unit bolus is to be delivered.

Each monthly prescription of V-Go consists of 30 V-Go devices and a filling device. Every 24 hours, the user attaches a filled V-Go device to clean skin and activates the needle button. The device begins to release insulin and continues for 24 hours. It is worn for the entire 24 hours (even overnight) and is then discarded. If desired, the V-Go can be filled with NovoLog insulin and left at room temperature for up to three days or in the refrigerator for up to five days, or can be filled with Humalog and left at room temperature or refrigerated for up to 24 hours.

Results of clinical trials

There are two studies on the V-Go's effect on blood glucose control. The first study included six people with diabetes who had been injecting a basal insulin, in some cases along with diabetes pills. These six people used the V-Go daily for seven days using NovoLog, a preset basal infusion rate, and up to three daily doses at mealtimes. Their fasting and premeal blood glucose levels and those

before lunch and dinner were similar to baseline, and postmeal, bedtime, and early morning (3 AM) levels trended lower when using the V-Go.

In the other published trial, 23 people with Type 2 diabetes, all taking different combinations of insulin and several different oral diabetes drugs, used the V-Go for 12 weeks. Their average A1C values improved when using the V-Go (from 8.8% to 7.6%) and worsened to 8.2% when use of the V-Go was discontinued. On a scale of 1 to 10, with 10 being the most positive, at the end of the trial the average overall patient experience rating for the V-Go was 9.1. Ratings were similarly positive when participants were asked about how complicated, discreet, and comfortable it was.

Pros and cons

Some positive aspects of the V-Go device include the elimination of multiple daily injections, the easy delivery of insulin, and the lack of electronics, batteries, infusion sets, or a need to program the device. People using a V-Go have insulin available all day without having to carry supplies such as vials, syringes, pens, or needles. In addition, many users find it discreet and comfortable to use. Using the V-Go requires only one stick a day with a tiny needle, and it can be attached anywhere that insulin can be injected or infused, such as the abdomen or the backsides of the arms. For mealtime insulin, it allows the user to determine how many units of insulin to give in increments of 2 units with a maximum amount of 36 units of on-demand bolus dosing in 24 hours. In other words, you can push the “bolus delivery button” up to 18 times in every 24-hour period.

One limitation that people trying the V-Go may encounter is the need for hands-on training and practice with the device to become comfortable with it. The V-Go is simpler than traditional pumps, but multiple steps are still needed to prepare the device for use, and mistakes are possible; for example, accidentally pressing the “needle release button” will render that patch pump unusable. For every 2 units of bolus insulin needed, both the “bolus ready” and the “bolus delivery” buttons need to be pressed. The more bolus insulin you require, the more times the buttons will need to be pressed. For example, if you were injecting 12 units of insulin with a meal, you would have to press these two buttons six times each (a total of 12 presses) to deliver 12 units of insulin. If you were injecting 12 units three times a day, that would translate to 36 presses to deliver a total of 36 units of bolus insulin for the day. The area of skin where the adhesive attaches the V-Go to the body may become irritated and develop mild swelling and redness, and may have a sticky residue. It’s also important that V-Go users still know how to give themselves insulin using either syringes or pens as a backup.

People who require greater than 40 units of basal insulin a day or 36 units of bolus insulin can’t use the V-Go. Likewise, people who require less than 20 units of basal insulin a day or require bolus doses in increments smaller than 2 units are not candidates for this device.

The cost for a 30-day supply of the device is approximately $250, but many health insurance plans will cover most of the cost. A supply of two to three vials of rapid-acting insulin per month is also required.

Looking forward

There are other patch pumps not yet available in the United States that may increase the insulin delivery device options available for people with Type 2 diabetes in the future. Finesse, from Calibra Medical (recently acquired by Johnson & Johnson), was approved by the FDA in 2010 but is not yet being marketed. The PaQ, from the Swiss manufacturer CeQur, has received approval in Europe but has not yet applied in the United States. The Solo patch pump, made by Medingo and purchased by Roche in 2010, received FDA approval in 2009 but is also not yet available for purchase. Other companies are also in various stages of developing patch pump technology.

Who should try a patch pump?

Patch pumps offer an alternative to a traditional insulin pump or syringes and pens for adults with Type 2 diabetes who require insulin therapy. If you're having a hard time controlling your blood glucose level with oral medicines, or if you've already been prescribed insulin but are reluctant to take it, a patch pump might be a useful tool for you.