Insulin Pump Class: Back to the Basics of Pump Therapy

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In the early 1960s, Dr. Arnold Kadish developed the first insulin pump, which was the size of a Marine backpack.¹ Over the years, insulin pumps have become much more refined and have decreased in bulk to the size and weight of a small pager. Insulin pump therapy, also known as continuous subcutaneous insulin infusion, is no longer seen as experimental and controversial, but rather is viewed as an acceptable alternative to multiple daily injection (MDI) therapy in the management of insulin-dependent diabetes² (Table 1).³

The insulin pump is an electro-mechanical device that mimics the body's natural insulin secretion from pancreatic β -cells by subcutaneously delivering rapid-acting insulin both at preset continuous basal rates and in extra bolus doses at mealtimes on demand.⁴ Insulin pumps allow for up to 24 different hourly basal rates in a 24-hour period. For bolus doses, pump users input their current blood glucose level and the number of carbohydrates they will consume, and the pump customizes their dose based on insulin currently on board (i.e., the remaining active insulin from the previous dose), their individualized insulin-to-carbohydrate ratio, and their individualized insulin sensitivity factor (i.e., their expected drop in blood glucose from 1 unit of insulin).^{1,5} Thus, insulin pumps are able to deliver insulin in a more physiological manner than other injection-based insulin regimens.⁵

In the late 1970s, results of the first human trials of insulin pump therapy were published. This was followed by numerous additional studies comparing insulin pump

therapy to traditional MDI regimens with regard to long-term glycemic control and minimization of hypoglycemia.^{6–11} Then, in 1993, the Diabetes Control and Complications Trial¹² confirmed the importance of intensive glycemic control using either insulin pump therapy or an MDI regimen along with frequent self-monitoring of blood glucose (SMBG).

In patients with type 1 diabetes, pump therapy has been shown to limit excess weight gain, reduce the frequency of severe hypoglycemia, and lower A1C levels.¹³ Pump therapy is also a therapeutic alternative for insulin-requiring patients with type 2 diabetes, especially those who require large amounts of insulin, have severe insulin resistance, and have poor glycemic control,^{14,15} and has been observed to reduce insulin requirements and lower A1C levels in patients with type 2 diabetes.^{14,16} Compared to MDI, insulin pump therapy allows for greater flexibility with timing of meals, reduces the risk of exercise-induced hypoglycemia, allows for overnight glycemic control, and gives patients greater ability to manage their own diabetes.¹³

Insulin pumps consist of a reservoir, a pump, and an infusion set. The reservoir, which is similar to a syringe, holds a 2- to 3-day supply of insulin and is placed into the battery-powered pump. The infusion set consists of tubing that connects the reservoir to a cannula (i.e., a tiny tube to deliver insulin subcutaneously) and transports the insulin from pump to patient. A small piece of adhesive holds the cannula in place at the insertion site.¹

Table 1. Comparison of Current Insulin Pumps³

Company/Pump	Reservoir Information	Infusion Set Information	Meter Interaction Information	Additional Product Details
Roche Insulin Delivery Systems/ Accu-Chek Combo	315-unit cartridge	Compatible with all standard Luer-lock connectors (a specific type of connector with a locking mechanism)	Yes; Accu-Chek Aviva Combo meter remote sends results wirelessly to pump	<ul style="list-style-type: none"> • Meter remote and pump can each control nearly all pump functions • Works from 6 ft. away • Watertight up to 8 ft. deep for 1 hour • Protective “skins” available • Works with Accu-Chek 360° software, insulin pump configuration software, and Smart Pix device reader for data management • Compatible with Windows (except Windows 7), but not with MacIntosh operating systems
Sooil Development/ Dana Diabcare IIS	300-unit cartridge	Compatible with Sooil infusion sets only	No	<ul style="list-style-type: none"> • Menu uses icons instead of words • Does not work with data management software
Medtronic Diabetes/ MiniMed Paradigm Revel	Model 523: 176-unit reservoir Model 723: 176- or 300-unit reservoir	Compatible with Medtronic infusion sets.	Yes; Contour Next Link meter wirelessly sends results to pump	<ul style="list-style-type: none"> • Built-in continuous glucose monitoring technology • Pump disconnects for bathing or swimming • Protective “skins” available • Works with CareLink Personal software • Compatible with Windows (including Windows 7 and Vista) and MacIntosh operating systems
Insulet/Omnipod	Pod (wireless insulin pump) includes built-in reservoir that holds 200 units	Does not use tubing; Pod comes with a built-in infusion set, cannula, and automated inserter	Yes; FreeStyle blood glucose meter is built into the Personal Diabetes Manager (device to wirelessly program insulin delivery)	<ul style="list-style-type: none"> • No tubing required • Pod and PDM to control pod's functions • Waterproof for up to 2.5 ft. deep for 1 hour • Protective “skins” available • Works with Abbott's CoPilot data management software • Compatible with Windows (except Windows 7), but not with MacIntosh operating systems
Animas/ OneTouch Ping	200-unit cartridge	Compatible with all standard Luer-lock connectors	Yes; meter remote sends results wirelessly to pump	<ul style="list-style-type: none"> • Meter remote and pump can each control nearly all pump functions • Meter remote works up to 10 ft. away • Pump is waterproof for up to 12 ft. deep for 24 hours • Protective “skins” available • Works with ezManager Max data management software • Compatible with Windows (except Windows 7) and MacIntosh operating systems
Tandem Diabetes Care/T:slim	300-unit cartridge	Compatible with all standard Luer-lock connectors	No	<ul style="list-style-type: none"> • Color touch screen and rechargeable battery • Pump is waterproof for up to 3 ft. deep for 30 minutes • Works with T:Connect Therapy Management • Compatible with Windows and MacIntosh

operating systems	<ul style="list-style-type: none"> • Patch pump specifically designed for use in adults with type 2 diabetes; not recommended for people with type 1 diabetes • Delivers insulin with button presses instead of electronics • Each patch is used for 24 hours and then disposed of and replaced • Pump is waterproof for up to 3 feet, 3 inches deep for 24 hours • No data management software
No	
Does not use tubing; pump comes with a built-in infusion set, cannula, and automated inserter	
V-Go 20: 20 units V-Go 30: 30 units V-Go 40: 40 units	
Valeritas/V-Go	

The needle of the infusion set can be inserted into the abdomen, upper thigh, or upper arm. The infusion set and reservoir must be changed every 2–3 days.

The indications for insulin pump therapy include inadequate glycemic control (defined as an A1C > 7%, the dawn phenomenon [early-morning increase in blood glucose], and marked variability in glucose from day to day); hypoglycemic episodes requiring assistance or hypoglycemia unawareness; the need for flexibility in lifestyle; and pregnancy or intention to become pregnant.^{13,17} All candidates should have the willingness and ability to learn how to use an insulin pump and to perform SMBG multiple times per day.^{1,4} Patients with significant psychological problems such as psychosis or severe depression are not appropriate candidates.⁴

Ongoing education, motivation, and psychological support are required for patients to succeed with insulin pump therapy. Patient education should include the principles of basal-bolus insulin therapy, sick-day management, carbohydrate counting, glucagon administration, site preparation and infection prevention, prevention and treatment of hypo- and hyperglycemia, and insulin adjustments for exercise.¹⁷ The most crucial factors for patient success are patients' willingness to perform frequent SMBG and sufficient ongoing clinical support.¹⁷

Program Background

The Longstreet Clinic (TLC) is a regional multidisciplinary physician practice. The Internal Medicine (IM) and Family Medicine (FM) departments are located in Gainesville and Oakwood (Hall County), Ga. Hall County is located in northeast Georgia 50 miles northeast of Atlanta. The population of Hall County is ~ 187,700.

Within the IM and FM departments, the Diabetes Education and Medical Nutritional Therapy department provides diabetes education and management services for patients with diabetes. Within this department, there is an interdisciplinary team of certified diabetes educators (CDEs) composed of a registered

nurse (team leader), a registered dietitian, and a pharmacist, all of whom are certified insulin pump trainers. The department offers various services, including individual and group diabetes education, gestational diabetes education and management, pediatric obesity education classes, and insulin pump therapy education and management.

Approximately 20% of all IM and FM patients have diabetes. Forty-seven percent of these diabetes patients are on insulin therapy, of which 3% use an insulin pump. For patients on insulin pump therapy, 99% use the MiniMed Paradigm Revel insulin pump and 1% use other brands of insulin pumps. All insulin pump patients are referred to the diabetes education department for pre-pump, pump start, and follow-up training sessions. After the initial training sessions, many of the insulin pump patients continue to be seen by the diabetes education staff for review of insulin pump downloads and adjustment of pump settings.

The lead CDE conceived the insulin pump class after several patients on pump therapy had severe hypoglycemic episodes while driving. She identified the need for insulin pump patients to have follow-up training to review insulin pump survival skills and prevent future hypoglycemic emergencies. A database search of IM and FM patients was completed to identify the subset of patients on insulin pump therapy.

Via phone or during office visits, CDEs invited established insulin pump patients identified through the database search to attend the class. All insulin pump patients were invited to the subsequent insulin pump classes. Baseline characteristics of the patients who attended the class are described in Table 2.

To assist with class attendance, patients received a reminder call 1 day before class.

Although initial education for insulin pump therapy focuses on the basics of pump operation, the class provides more in-depth education about sick-day management, infusion site problems, and additional keys to pump success. The objectives of the class are to review insulin pump sur-

Table 2. Baseline Demographics of Class Participants

Characteristic	Frequency
Type of Diabetes	
Type 1	18/35
Type 2	17/35
Sex	
Female	22/35
Male	13/35
Race	
African American	3/35
White	32/35
Age (years)	
30–35	2/35
40–49	6/35
50–59	10/35
60–69	12/35
70–79	5/35

vival skills for new and experienced pump patients to prevent emergency room visits, improve glycemic control (as measured by A1C), and provide patient satisfaction.

Insulin Pump Class Structure

Each class takes 90 minutes. All patients who have attended the class use the MiniMed Paradigm Revel insulin pump system, so the educational materials discussed during the session focus on this product. When patients arrive for class, a CDE downloads their insulin pump. While insulin pumps are being downloaded, another CDE begins the interactive educational roundtable, which focuses on insulin pump survival skills. Topics for the roundtable include:

- Advanced carbohydrate counting using food models
- Battery changing and adjustment of pump settings
- Diabetic ketoacidosis prevention
- Troubleshooting unexplained high blood glucose levels
- Prevention and treatment of hypoglycemia

- Infusion site care: infusion set types and sites and infection prevention

Although these topics are discussed during the initial insulin pump training, material is covered in more depth in class, and participants can share their experiences. In addition to these discussions, patients are also given survival skills kits that contain written handouts about these topics to enforce learning. The kits also contain glucose tablets, a diabetes driver decal, and a bag of U-100 insulin syringes. After the roundtable discussion, adjustments to insulin pump settings are made as needed with CDEs and each patient individually. Patients are given a copy of their insulin pump settings.

As the class comes to an end, patients complete a post-class satisfaction survey and are given a follow-up appointment.

Outcomes

As the class was developed, the initial goal was to enroll six insulin pump patients every 6–8 weeks, with the first session to be held in July 2011. From July 2011 to May 2013, 10 sessions have been held, with a total of 30 participants completing the class. Although the initial goal was to have six insulin pump patients per class, actual class size has varied from two

to six participants (Table 3). The outcomes data collected for the class included pre- and post-class A1C values, pre- and post-class emergency room visits, and post-class satisfaction (Tables 4–6).

A1C results

The average pre- and post-class A1C levels were calculated based on the pre- and post-class A1C levels for each participant. As demonstrated in Table 4, the overall average pre-class A1C has been 7.4%, with an overall average standard deviation of 0.44. The overall average post-class A1C has been 7.2%, with an overall average standard deviation of 0.2.

Emergency room visits

The initial assessment of emergency room visits was the number of visits in the 12 months before the class date. For the 35 patients enrolled in the class, there had been a total of four emergency visits, two of which were diabetes-related. Tracking of post-class emergency room visits is ongoing. To date, there has been only one emergency room visit by a class participant, and that visit was diabetes-related.

Satisfaction survey

Participants who completed the survey in the class found the roundtable discussions, handouts, and visual aids to be helpful. The majority of participants who completed the survey (92.9%) learned at least one new skill for their insulin pump therapy. All respondents felt that what they learned will help them manage their insulin pump therapy and that their questions were answered. All survey respondents agreed to put their survival kit together and said they would recommend the class to others (Tables 5 and 6).

Challenges and Ongoing Development

Although these results indicate that the class has been successful, there are several limitations. The sample size for the class is relatively small. Additionally, the timeframe for measuring the impact of the class on A1C level and number of emergency room visits has been short. Overall, participants in this class were already

Table 3. Insulin Pump Class Attendance

Class Date	Actual Attendance/ Goal Attendance
July 2011	6/6
August 2011	6/6
September 2011	3/6
October 2011	4/6
December 2011	3/6
March 2012	3/6
April 2012	2/6
September 2012	4/6
April 2013	2/6
May 2013	3/6

Table 4. Differences in Participants' Pre- and Post-Class A1C Levels

Class Date	Pre-Class A1C (mean %)	Pre-Class Standard Deviation	Post-Class A1C (mean %)	Post-Class Standard Deviation
July 2011	7.1	0.43	7.4	0.42
August 2011	7.5	0.55	7.5	0.40
September 2011	7.0	0.85	6.9	0.94
October 2011	7.4	0.51	7.0	0.35
December 2011	8.0	0.10	7.4	0.65
March 2012	7.2	0.51	7.4	0.92
April 2012	7.4	0.05	6.4	0.00
September 2012	7.4	0.90	6.8	0.25
April 2013	6.6	0.20	6.4	0.20
May 2013	8.3	0.28	8.5	1.77
Overall	7.4	0.44	7.2	0.2

Table 5. Class Participant Post-Class Survey, Part A (n = 28)*

Item	Likert Scale Results				
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Roundtable discussion was helpful	0	0	0	4	24
Handouts and visuals were helpful	0	0	0	5	23
I learned at least one new skill for my insulin pump therapy	0	1	1	3	22
What I learned will help me manage my insulin pump therapy	0	0	0	5	23
My questions were answered	0	0	0	3	25

*Although 35 participants completed the class, 28 participants completed the survey.

Table 6. Class Participant Post-Class Survey, Part B (n = 28)*

Item	Yes	No
I will put my survival kit together	28	0
I will recommend this class to others	28	0

*Although 35 participants completed the class, 28 participants completed the survey.

compliant to their insulin pump therapy regimen.

CDEs are working to identify additional pump patients to enroll in the class, with the ultimate goal of having all insulin pump patients in the medical practice complete the course to improve glycemic control (as indicated by the A1C), reduce the number of diabetes-related emergency room visits, and ensure patient satisfaction with the class.

The CDE team is also considering the addition of insulin pump “happy hours” on Friday afternoons as a drop-in option for patients who are unable to attend the scheduled class.

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