What do insulin pumps offer in diabetes care?

ALICIA JENKINS MB BS, MD, FRACP, FRCP
DAVID O'NEAL MB BS, MD, FRACP

Insulin pumps are usually recommended by healthcare professionals and used by people with type 1 diabetes who desire to improve their blood glucose control and quality of life, and increase flexibility in their lifestyle and diet. Pump therapy can particularly benefit people with highly variable schedules, those who exercise or travel often, those who have recurrent severe hypoglycaemia events and/or reduced hypoglycaemia awareness, women desiring pregnancy, and the very young. A multidisciplinary clinical care team, including GPs, is required to support use of pump therapy.

Key points

- **Over 10% of people in Australia with type 1 diabetes, in particular those under 25 years of age, choose insulin pump therapy rather than multiple daily insulin injections.**
- **Careful patient selection and input by a multidisciplinary pump-experienced diabetes care team, including the GP, is required for optimal clinical benefit.**
- **User or carer input, good carbohydrate counting skills and frequent home blood glucose monitoring are required to optimise glycaemic control.**
- **Insulin pumps do not control glucose levels automatically and, although there are improvements, there are still significant demands on the patient.**
- **Some insulin pumps can be integrated with a continuous glucose monitor, which measures interstitial fluid glucose levels.**

ENDOCRINOLOGY TODAY 2013; 2(4): 27-30

Dr Jenkins is a Professor of Diabetes and Vascular Medicine at the NHMRC Clinical Trials Centre, The University of Sydney, Sydney; an Honorary Professor in the Department of Medicine (St Vincent's), The University of Melbourne; and an Endocrinologist in the Department of Endocrinology and Diabetes, St Vincent's Hospital, Melbourne. Dr O'Neal is an Associate Professor in the Department of Medicine (St Vincent's), The University of Melbourne; an Endocrinologist in the Department of Endocrinology and Diabetes, St Vincent's Hospital, Melbourne; and a General Physician/Endocrinologist at the Werribee Mercy Hospital, Melbourne, Vic.

Insulin pump therapy, also known as continuous subcutaneous insulin infusion (CSII) therapy, for people with type 1 diabetes has substantially improved since it first became available for clinical use in Australia over 30 years ago. Today's pumps are smaller, more reliable and have many more features. The insulin infusion lines are more comfortable and less likely to block than earlier versions. Currently, over 11,000 people in Australia with type 1 diabetes (approximately 10% of all people with type 1 diabetes) use an insulin pump.[1] Most insulin pump users are women and about half of all pump users are under 25 years of age. About 40 to 50% of children with type 1 diabetes use insulin pumps and many middle-aged and older people with type 1 diabetes are also pump users.

An estimated 140 people commence CSII therapy each month in Australia, with a low (2%) permanent discontinuation rate nationally.[1] GPs are increasingly likely to provide healthcare for patients with type 1 diabetes who are using, or may wish to use, CSII therapy owing to:

- paediatric patients who use a pump 'growing up'
- increasing uptake of pumps during adulthood
- advances in the technology
- the rising incidence of type 1 diabetes (at about 3% per annum in Australia).

Although this insulin delivery mode is occasionally used by pregnant women with gestational diabetes or pre-existent type 2 diabetes, this article focuses on patients with type 1 diabetes as they make up the majority of insulin pump users in Australia.

Desirable characteristics of insulin pump users

- Type 1 diabetes and a desire to improve glucose control or quality of life
- Realistic expectations of pump therapy
- Adequate vision
- Manual dexterity
- Intellectual, numeracy and problem-solving skills
- Good carbohydrate counting skills
- Good general diabetes knowledge
- Preparedness to undertake frequent home blood glucose testing
- Blood ketone testing skills
- Healthy skin at insertion sites
- Adequate time to commence a pump and for regular follow up
- Support from an experienced multidisciplinary diabetes care team, including GPs
- Family support (for children and adolescents)

Characteristics of insulin pump users

CSII therapy is usually recommended by healthcare professionals and desired by people with diabetes to improve their blood glucose control (to reduce episodes of hypoglycaemia and risk of long-term complications), increase their flexibility in lifestyle and diet, and improve their quality of life. Pump therapy can be of particular benefit to: people with highly variable schedules; those who exercise or travel often; those who have recurrent severe hypoglycaemia events and/or reduced hypoglycaemia awareness; women with type 1 diabetes desiring pregnancy; and the very young with type 1 diabetes.

Desirable characteristics of CSII users are summarised in the box on this page. Unfortunately, adequate finances are also required for pump acquisition and ongoing use as the government currently does not provide insulin pumps to all who might benefit. Most people with diabetes acquire their pump via private health insurance, and running costs are usually higher than with multiple daily insulin injection (MDI) therapy (see text below).

With children and adolescents it should be clarified that they understand about insulin pump therapy and are interested in using a pump, and are not just responding to parental interest. Very young children will need substantial support from their parents or carers to support their pump use. Clinician awareness and sensitivity are needed if problems such as loss of vision, reduced manual dexterity or intellectual impairment threaten the necessary skills of an existent pump user.

People who use pumps should expect excellent knowledge and skills from their pump-related care providers as recently outlined by an Australian CSII working group.[2]

CSII therapy: advantages and disadvantages

Advantages

The frequency of injections is reduced from 28 per week for a person on a basal bolus four injections a day regimen to two a week for a person using an insulin pump. CSII therapy is usually associated with better quality of life and improved blood glucose control for the user, including similar or less frequent episodes of severe hypoglycaemia. Some of these benefits may relate to the extra education and support provided by the diabetes care team related to pump use.

A meta-analysis of the international literature on randomised trials of CSII versus MDI therapy reported a mean HbA_{1c} reduction of 0.3% with CSII therapy;[3] however, audits of several Australian paediatric and adult clinics reveal a mean HbA_{1c} drop of over 0.6%, which is often sustained for years.[4-6] On an individual basis, HbA_{1c} reductions of 2% or more are not rare. In some people experiencing frequent episodes of hypoglycaemia, an increase in HbA_{1c} is desirable and HbA_{1c} levels should not be the sole reason for CSII use or outcome for assessment.

On average, weight does not change significantly with pump use. In the authors' recent audit (mean 3.9 years of follow up) of 77 adult patients with type 1 diabetes and a mean HbA_{1c} of 7.7% changing from MDI to CSII therapy, a decrease in HbA_{1c} by a mean of 1.1% was shown. Weight, lipid levels, blood pressure and albuminuria did not change significantly with CSII therapy.[5]

Disadvantages

Disadvantages of insulin pump therapy include the need to wear an external device, skin irritation or infections at insertion sites, episodic pump failures, and increased cost (for the individual and the healthcare system). The healthcare system cost may include additional clinician time to support patients commencing CSII therapy, as well as the provision of the pump and subsidised consumables. Relative to MDI therapy, if insulin delivery is interrupted (such as due to malfunction) CSII use is associated with a more rapid onset of hyperglycaemia and ketosis. People who use insulin pumps should therefore be advised, prescribed and reminded to always carry a back-up means of insulin delivery (e.g. an insulin pen). Although early reports suggested increased rates of diabetic ketoacidosis with insulin pump therapy versus MDI therapy, that is no longer the case, with lower rates of diabetic ketoacidosis now reported in people who use insulin pumps.[4]

The current pump technology and how to acquire it

About insulin pumps and the terminology

An insulin pump is a small portable battery driven (AA or AAA) device that houses a disposable reservoir for rapid-acting insulin. It has a driver mechanism to precisely deliver small insulin doses and in-built programs to precisely control insulin delivery and to recommend and deliver (on user initiation) insulin boluses to correct hyperglycaemia and cover carbohydrate intake. A range

of insulin infusion lines (specific to the insulin pump company) and cannulas ('delivery sets'), which the patient or carer inserts into the subcutaneous tissue, usually in the abdomen or buttock region, are available in a range of tubing lengths, insertion needle and cannula sizes and insertion angles. There are devices to assist insertion and adhesive tapes to secure the cannula and tubing. The user or carer fills the reservoir with insulin from standard 3 or 10 mL rapid-acting insulin vials, and the line should be changed approximately every three days using an aseptic technique. Care with reservoir filling and line priming with insulin at room temperature will minimise bubble formation, which can interrupt insulin delivery. Batteries usually need replacement every two weeks.

Commonly used insulin pump terms are summarised in the box on this page. Insulin pumps have in-built programs to control insulin delivery, which the user or carer can alter directly on the pump. Approximately half the daily insulin requirement is given as background basal insulin, with there usually being four to six different insulin infusion rates ('basal rates') across the day. Users can choose to run a lower or higher than usual ('temporary') basal rate, such as for exercise or on less physically active or sick days. Insulin boluses are initiated by the wearer (or carer of a young child) to cover food or correct hyperglycaemia, and this can be guided by an inbuilt 'bolus calculator', which bases recommendations on users entering their blood glucose reading, their estimate of the carbohydrate content of the food to be eaten, and the individualised estimates of insulin sensitivity, insulin action time and target glucose levels. These calculators consider recently delivered insulin and can reduce the risk of excess insulin delivery and resultant hypoglycaemia.

Basal rates and other pump settings are usually established initially by the patient and his or her diabetes team (usually a CSII experienced doctor, certified diabetes nurse educator and dietitian). Pump settings should be reviewed regularly because they often change, such as in relation to changes in weight, hormones, fitness, lifestyle, stress and intercurrent illness. All insulin pump data can be 'downloaded' from home or the clinic via the internet for review and analysis by users and their diabetes care team. The pump data that can be downloaded include: pump settings, basal and bolus insulin delivered, bolus calculator use (and over-rides), blood glucose levels, estimated meal carbohydrate content (entered by the user), infusion line changes and pump suspensions. If the pump is used with a continuous glucose monitor then the interstitial fluid glucose level data can also be downloaded.

Potential integration with a continuous glucose monitor

As described above, current insulin pumps do not automatically sense ambient glucose levels and deliver the required insulin. This 'artificial pancreas' is still in development, including some research being conducted in Australia. Insulin pumps are still patient-controlled devices and are not 'less work' than MDI therapy, nor do they remove the need for regular blood glucose testing.

Glossary of insulin pump-related terms

Reservoir: disposable plastic canister to contain insulin in a pump.

Infusion set: disposable plastic tubing and cannula (with insertion needle) that delivers insulin from the reservoir to the subcutaneous tissue.

Basal rate: (low) rate of insulin delivery at a constant rate per hour. Usually basal rates are set for at least three to four hours or more, and people usually have four or more basal rates over a 24-hour period.

Temporary basal rate: a short-term (usually several hours) different basal rate of insulin delivery, usually expressed as a percentage of the usual basal rate, to prevent low glucose levels around exercise or to control higher glucose levels during illness or less physically active days.

Insulin bolus: insulin given to cover food intake or to correct a high blood glucose level.

Bolus calculator: in-built calculator in the pump that the operator can use to suggest an insulin dose to cover food intake or correct a high glucose level. The calculator is individualised, usually with input from the diabetes care team.

Insulin carbohydrate ratio: the estimated number of grams of carbohydrate in food that one unit of insulin will cover. People often have a different insulin carbohydrate ratio for different times of day.

Insulin sensitivity or insulin correction factor: the estimated decrease in blood glucose level (mmol/L) brought about by one unit of insulin in an individual.

Insulin action time: the time that the rapid-acting insulin is predicted to have significant glucose lowering effects in the pump user (usually between three and five hours).

Target glucose level: the range of blood glucose that the insulin pump will use to aim for in its bolus calculator. It is usually narrower than the blood glucose target range that the patient is aiming for.

Some insulin pumps can be integrated with a company-specific continuous glucose monitor system in which a subcutaneous sensor, based on glucose oxidase methodology as used in blood glucose test strips, measures interstitial fluid glucose levels every few minutes and displays the reading on the pump screen. Stand-alone continuous glucose monitor devices are also available. There is a time and absolute value difference between glucose levels in the blood and interstitial fluid, so daily blood glucose estimations when glucose levels are not rapidly changing are needed to calibrate the continuous glucose monitor. Users should base decisions on treatment of

hyperglycaemia or hypoglycaemia on blood glucose levels.

The authors and colleagues have developed and evaluated an algorithm to guide patients with type 1 diabetes using insulin pumps and a continuous glucose monitor as to how to respond to the resultant abundant glucose data. This algorithm and teaching documents are available free online at www.diabetesccre.unimelb.edu.au.[7,8] Some recently available blood glucose meters can wirelessly transmit patient performed blood glucose results to the insulin pump. Continuous glucose monitor systems can provide alarms if interstitial fluid glucose levels are high, low or rapidly changing, and in the case of one pump (so far) can suspend insulin delivery for up to two hours in the setting of a very low interstitial fluid glucose level and the absence of a response by the wearer to the alarms. Continuous glucose monitor technology is expensive, with each disposable glucose sensor alone (lasting six to seven days) costing approximately $75 with there being no subsidy for their use.

Companies providing insulin pumps, how to acquire them and costing

There are currently three companies providing insulin pumps products in Australia: Animas, Medtronic and Roche. Additional options are available overseas. An insulin pump costs approximately $9000 and most people acquire them via private health insurance, which will support a pump purchase every five years on medical request. A recent, currently inactive, government program provided some pumps to children with type 1 diabetes on a means-tested basis.

Pump reservoirs and lines are subsidised by the government (via the National Diabetes Services Scheme) for insulin pump users with type 1 diabetes. Nevertheless, CSII therapy is more costly to the user than MDI therapy, estimated at $29 versus $6 per month.[1] Continuous glucose monitor systems are currently entirely self-pay, hence not affordable for most patients.

Starting insulin pumps and ongoing education

Starting an insulin pump is a journey over months, not days, which begins with the potential user (and carer if relevant) achieving realistic expectations of the practicalities, benefits and disadvantages of pump therapy, and (if not already in place) acquiring very good diabetes care knowledge, carbohydrate counting and blood ketone testing skills. Ongoing education is usually needed, for example, to increase ability to adjust pump settings and to use different insulin bolus delivery patterns, such as bolus delivery over hours rather than seconds for certain types of meals, such as pizza, or for meals spread over several hours.

CSII therapy should be commenced and followed up by a multidisciplinary team experienced in the use of insulin pumps, including: a specialist (usually an endocrinologist or a paediatrician); a certified diabetes educator; a dietitian; often an insulin pump company trainer; the GP; and other clinicians involved in the user's healthcare. Management by a primary care team alone is not recommended because of the complexity, specialised knowledge and time required.

Once the patient is through the time-consuming pump pre-education phase, pump start and initial follow up (which usually occurs over multiple face-to-face visits and phone and electronic communication over several months), regular assessment of pump use and insertion sites, along with other diabetes care, is recommended, usually every three to six months for adults and every two to three months for children.

More information related to CSII therapy is available from Diabetes Australia, diabetes clinics offering pump therapy, the pump manufacturers, dedicated textbooks (e.g. via the American Diabetes Association [www.diabetes.org]), diabetes journals, short training courses and experienced CSII users.

Summary

In summary, insulin pumps are becoming increasingly common in diabetes care in Australia. All clinicians involved in the care of people with type 1 diabetes, not only endocrinologists, should have an interest in, and relevant level of knowledge of, CSII therapy. Unfortunately this option of delivering life-saving insulin is not currently available to all people in Australia who might benefit. Inequities in access related to financial requirements and local CSII knowledgeable clinicians (or shared-care via telemedicine) need to be addressed. **ET**

References

1. Australian Institute of Health and Welfare. Insulin pump use in Australia. Diabetes series no.18. Cat. No. CVD 58. Canberra: AIHW; 2012.
2. The Australian National Adult Insulin Pump Therapy Working Group. Provision of quality care for adults with type 1 diabetes requiring insulin pump therapy. InfuSystems Asia 2013; 8(1): 1-6.
3. Misso ML, Egberts KJ, Page M, O'Connor D, Shaw J. Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. Cochrane Database Syst Rev 2010; (1): CD005103.
4. Johnson SR, Cooper MN, Jones TW, Davis EA. Long-term outcome of insulin pump therapy in children with type 1 diabetes assessed in a large population-based case-control study. Diabetologia 2013 Aug 21 [Epub ahead of print].
5. Calandro DA, Januszewski AJ, Cuper KK, et al. Better than international average HbA1c reductions in Australian insulin pump service for adults with type-1 diabetes. Abstract (oral presentation). ADS/ADEA Conference, Sydney, August 2013.
6. Cohen ND, Hong ES, Van Drie C, Balkau B, Shaw J. Long-term metabolic effects of continuous subcutaneous insulin infusion therapy in type 1 diabetes. Diabetes Technol Ther 2013; 15: 544-559.
7. Jenkins AJ, Krishnamurthy B, Best JD, et al. Evaluation of an algorithm to guide patients with type 1 diabetes treated with continuous subcutaneous insulin infusion on how to respond to real-time continuous glucose levels: a randomized controlled trial. Diabetes Care 2010; 33: 1242-1248. Erratum in: Diabetes Care 2010; 33: 1911.
8. Jenkins AJ, Krishnamurthy B, Best JD, et al. An algorithm guiding patient responses to real-time-continuous glucose monitoring improves quality of life. Diabetes Technol Ther 2011; 13: 105-109.

COMPETING INTERESTS: Dr Jenkins and Dr O'Neal have received research funding from Medtronic, Eli Lilly, Novo Nordisk and Sanofi-Aventis and honoraria from Medtronic. Dr Jenkins has also received honoraria from Animas.