

Since the insulin pump made its debut about 30 years ago, it has received mixed reviews. Dr Warren Lee, consultant paediatric endocrinologist of Dr Warren Lee's Paediatrics, Growth & Diabetes Centre, takes a look at the track record of the pump which has been used by athletes, beauty queens and jetsetters.

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Insulin Pumps: **Shrinking in Size, Growing in Stature**

Insulin pumps are a type of insulin delivery device that can help patients control their diabetes more effectively and can prevent hospital admissions due to hypoglycaemia as well as reducing long term microvascular and macrovascular complications.

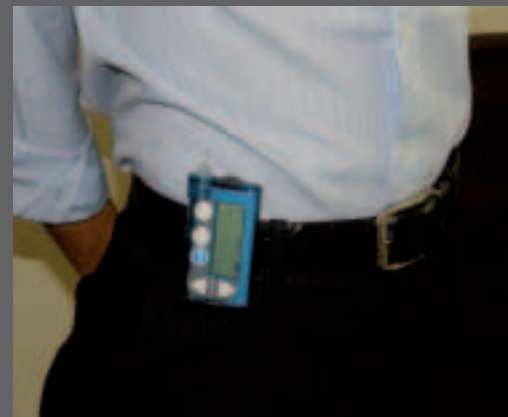
Insulin pumps have been in use since the 1970s. They now have worldwide annual sales topping USD \$1.3 billion and are in use by an estimated 100,000 teenagers around the world. In Singapore, insulin pumps have been around for approximately nine years, with the first paediatric insulin pump user fitted out in KK Women's and Children's Hospital.

Since then, about 100 Singaporeans have been on insulin pumps; although insulin pumps are useful for both adults and children and for both type 1 and type 2 diabetes patients who have been unable to achieve glycaemic control using multiple daily insulin injection, the most rapid increase in the use of insulin pumps has been seen among paediatric type 1 diabetes mellitus patients.

few buttons on this automated machine. Besides the amount, the manner of delivery of the insulin can also be programmed. For example, the bolus, square wave and dual wave modes can deal with rapidly digested and also slowly digested foods.

Insulin pumps have shrunk in size, from the size of a haversack when it was first invented, to the current size which is no bigger than a mobile phone. It can be worn in the pocket or in a pouch under the clothes. You can run, walk, eat, sleep and do most things with it on. Most people would take it off when showering, swimming, or when performing very strenuous or intimate activities. It can be taken off for over 90 minutes without ill effect.

Insulin pumps are great for people who need to travel because they make it easier to deal with time zone differences. Insulin pumps are useful for women with gestational diabetes and diabetes in pregnancy, as they allow for much tighter glycaemic control and lower the risk of birth defects and adverse outcomes in diabetic pregnancies.



The UK's National Institute for Health and Clinical Excellence (NICE) is now recommending that insulin pump therapy be considered in adults and children 12 years or older with type 1 diabetes mellitus, if trials of conventional multiple daily injections have failed to control blood sugar levels, i.e. HbA1c levels have remained at 8.5% or above. NICE currently recommends the use of an insulin pump in patients who suffer repeated and often unpredictable hypoglycaemic attacks or whose fear of needles has had a negative impact on his or her life.

What is an insulin pump? Put very simply, an insulin pump consists of a pager-sized miniature computerised control system and a battery, a supply of insulin in a reservoir, coupled to a miniature pump (e.g. an electrical stepper motor), to deliver the insulin via into a catheter placed under the skin or subcutaneously. The user controls this miniature computerised device by pressing buttons on the pump or via a wireless remote control device like a wireless car key.

The device is programmable such that it can provide a constant or variable basal insulin infusion as well as a large bolus of insulin on demand, just by pressing a

Insulin pumps also free people to have a snack or choose to skip or delay a meal without having a high blood glucose or hypoglycaemic episode. They are invaluable to young serious athletes with very variable insulin sensitivities, or who have irregular meals, hours of sleep and type of activities.

Because they allow for easily programmable but precise changes in basal insulin and bolus insulin doses, they allow for tighter glucose control while overall reducing the risk of hypoglycaemia.

Using an insulin pump can be likened to using fire. Fire is a good servant but a bad master, and we need to recognise that insulin pumps are potentially dangerous, just as insulin itself is a potent and dangerous drug used in the wrong hands, but a life-saving medication when used correctly. Insulin pumps are also similar to musical instruments. Anyone can thump a few notes on a piano, but it takes training and practice to make beautiful music on the instrument. It also takes a good teacher and a committed student.

In a recent article, Cope et al (PEDIATRICS Vol. 121 No. 5 May 2008, pp. e1133-e1138) questioned the safety aspects of insulin pump use in adolescent patients. In the article, it was noted that in 2005 alone, the US Food and Drug Administration (FDA) received five death reports in which teenage insulin pump users may have been negligent or noncompliant with the use of the device.

While this sounds alarming, it represents a mortality rate of roughly 0.05 deaths per 1000 person years. This mortality rate is in fact low. Soedomah-muthu et al (Diabetes Care, 2008 Jul ;31(7): 1360-6) reported that the annual mortality rate of type 1 diabetic patients (15 to 61 years, mean age at baseline 33 yrs) was five per 1000 patient years. In another study from the Yorkshire Register of children and young adults with type 1 diabetes, Feltbower et al, (Diabetes Care, 2008 May ;31(5) : 922-6) reported a death rate of 1.7/1000 person years for subjects 0-14.9 years and 4.6/1000 person years in the age group 15 to 29 years, and concluded that subjects with type 1 diabetes diagnosed under 30 years of age had a 4.7 fold excess mortality risk compared to people without diabetes, with nearly half the deaths due to acute or chronic complications of diabetes.

Nevertheless, this series of deaths prompted a review of infusion pump-related adverse events among adolescents, which found that over a 10-year period from 1996 to 2005, there were 1594 injuries and 12 deaths in youths aged 12 to 21 years while users were on insulin pumps. In this series, 82% of cases involving insulin pumps resulted in hospitalisation. In 62% of cases, there was hyperglycaemia and 46.6% of these had diabetic ketoacidosis. However, only 31 reports cited a need for repair or replacement of the device and 19 reports were of device failure and failure to deliver insulin.

The report found that the most common causes of adverse incidents among the teenagers in the study were:

- 1 Lack of education or knowledge about proper pump usage and procedures
- 2 Non-compliance
- 3 Problems associated with sport and other activities
- 4 Device misuse.
- 5 Risk taking behaviours
- 6 Pubertal growth
- 7 Lack of parental supervision

In addition, we have to consider that adverse events may result from hardware and software problems and user problems, which can lead to over-delivery or under-delivery of insulin.

Over-delivery may result from:

- a. The user calculating or programming the wrong dose, either deliberately or by mistake
- b. Priming the pump with the insulin catheter connected to the body

Under-delivery may result from:

- a. Catheter related problems such as blockage, kinking, or leakage from an improperly affixed subcutaneous catheter or pump tubing (actually quite rare)
- b. Forgetting to bolus with meals (by far the most common problem)
- c. Forgetting to put back on or switch on the pump after temporarily stopping the pump for sports, etc
- d. Weak batteries, leakage from the reservoir, precipitated insulin
- e. Fibrosis at the infusion site

Several factors must be considered when a person with diabetes is being considered for an insulin pump. They include:

- a. Careful patient selection – for the level of understanding and motivation to adhere to the self care procedures involved, and the absence of risk taking behaviours such as substance abuse, uncontrolled alcohol use, and depression
- b. Availability of patient education before, during and after initiation of pump therapy
- c. Adequate skilled technical and medical support from the pump prescriber and equipment supplier
- d. A close relationship between the patient and the team caring for the patient

Physical proximity of the team to the patient is not as important as availability and accessibility of advice. You should also consider a trial of insulin pump therapy before making a decision to purchase a pump or go on long term pump therapy.

Insulin pump use should not be initiated casually, but only after careful assessment and selection of patients and their families and only after a careful and comprehensive patient education process. The quality of the diabetes care team and the backup from the insulin pump supplier are also important. The risk of diabetic ketoacidosis when insulin delivery is interrupted due to a pump malfunction is very real, and there is also a risk of over and under-treatment either due to patient or pump factors.

Is an insulin pump for you? Speak to a doctor familiar with insulin pumps and find out.

