Insulin Pump Therapy 101

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Insulin pump therapy, also referred as continuous subcutaneous insulin infusion or CSII, consists of a small computerised battery operated device that delivers fast acting insulin; its goal is to mimic the function of a normal pancreas via basal insulin delivery (small continuous dose of insulin to maintain glucose levels stable between meals and overnight) alongside with bolus doses as needed (to cover post prandial glucose spikes and to correct high blood glucose levels with the help of insulin sensitivity factor).

Fig. 1: Insulin Pump (pictorial representation)

Insulin Pump Development- A Long Journey

The field of glucose monitoring, and insulin administration technology has been transformed in the past couple of decades. Dr. Arnold Kadish introduced the first insulin pump in early 1960s. The earlier pump models were relatively large in size and had to be worn like a backpack. Obviously, they were awfully cumbersome and also could not guarantee safe insulin delivery, thus limiting their use to only difficult to manage patients. However, the technology continued to evolve and was introduced to treat patients with T1DM in the late 1970s.[1,2] These advances made satisfactory treatment of T1DM possible and set the stage for the DCCT (Diabetes Control and Complications Trial) study; interestingly, 59% of the patients in the intensively treated group were managed by CSII at some stage.[3]

Fifty years after its introduction, CSII today is widely used in clinical practice not only in Type 1 diabetes (T1DM), but also in Type 2 diabetes (T2DM) and various other forms of the disease - proven benefits. The increase in the CSII uptake is largely driven by three factors: the development of more reliable and advanced pump technology, an accumulating evidence base for the efficacy of pumps vs. multiple daily injection therapy and the issuing of national guidelines on the indications for using CSII, based on clinical benefit and cost-effectiveness.[4]

The earlier models of insulin pumps lacked a plethora of helpful features that are now standard in current day pumps such as various alarms for malfunction, low-battery state and cannula occlusion. In addition to alarms, notable developments in pump technology over the

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years include the introduction of flexible basal rates that allow patients to alter infusion rates both on demand and at a preset time of the night or day.

Continuous Glucose Monitoring (CGM) is the key for automation of Insulin Pump Delivery

CGM has expanded the capabilities of insulin pumps immensely. CGM is a method to track glucose levels in interstitial tissue every 5-15 minutes throughout the day and night. It also provides information regarding hourly, daily, and weekly glucose trends and patterns. Based on the glucose levels, the insulin pump algorithm can modulate the insulin delivery.[7,8] The development of CGM systems has enabled insulin pump technology to evolve and progress to the level of almost mimicking physiological requirements. All sensor-augmented insulin pumps help patients to see their glucose levels on their insulin pump or on a separate device (real time glucose monitoring) and alert them when their glucose levels are rising or falling. The insulin pumps using the predictive low glucose management algorithm even allows suspension of insulin delivery when sensor glucose is approaching a pre-set low limit and resume basal insulin automatically when the glucose recovers. The latest hybrid closed loop technology automatically adjusts insulin delivery every 5 minutes based on glucose levels. It helps people with diabetes achieve significantly higher time in range which means better glucose control with fewer highs and lows.[9]

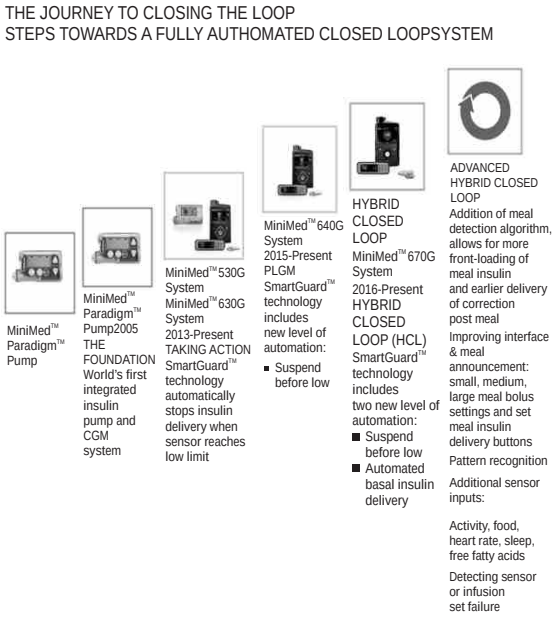

Fig. 2: Insulin Pump Development Journey

The sensor augmented pump therapy has been shown to be superior in terms of diabetes outcomes to the multiple daily insulin injection therapy in several high-profile clinical trials.[10,11] In both adults and children with poorly controlled T1DM, SAP therapy resulted in significant improvement in HbA1c levels, as compared with injection therapy. A significantly higher proportion of both adults and children in the insulin pump-therapy group than in the injection-therapy group reached the target glycated haemoglobin (HbA1c) levels.[10] Sensor-augmented insulin pumps that suspend insulin delivery, when the sensor glucose reaches low limit or predicted to go low within the next 30 min have been approved by the regulatory agency in India. The Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial of 247 patients with T1DM and documented

nocturnal hypoglycaemia showed that SAP therapy with a low-glucose suspend function significantly reduced nocturnal hypoglycaemia over 3 months without increasing HBA_{1C} levels.[12] These devices offer the opportunity to counter hypoglycaemia to help reach glycaemic targets.

Conclusion

Half a century after its introduction, world-wide use of insulin pump therapy is increasing, and clinicians in India should offer the modality to patients when indicated, especially in younger patients and those with T1DM. Benefits include lower rates of hypoglycaemia, superior glycaemic control and increased quality of life. Although both insulin pump therapy and multiple daily injections can achieve near-normoglycaemia without increased hypoglycaemia in some people with diabetes, insulin pump therapy is particularly effective in those who have had continued elevated HbA1c and/or disabling hypoglycaemia after best attempts with MDII. Automation of insulin delivery presents the next important step in winning the battle against diabetes.

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