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A Review On Insulin Pump Therapy

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Abstract- Insulin pump therapy, clinically known as Continuous Subcutaneous Insulin Infusion (CSII), represents a sophisticated shift in diabetes management from conventional multiple daily injections (MDI). By delivering a continuous supply of rapid-acting insulin through a subcutaneous cannula, the therapy more closely mimics the physiological insulin secretion of a healthy pancreas. The current data indicate there are over 1 million people with diabetes on insulin pump therapy worldwide3 and 350,000 to 515,000 in the United States4. Insulin pump therapy offers increased lifestyle flexibility and improved glucose management. The goal of this paper is to outline the topics that should be covered by diabetes care and education specialists when teaching people with diabetes (PWD) and their families or significant others. It focuses on insulin pump therapy and the importance of maintaining a high level of expertise in this subspecialty of diabetes education if choosing to include pump and sensor training in the individual specialist's practice.

Keywords- Insulin Pump Therapy, (CSII), Diabetes Mellitus, Patient Education, Insulin Delivery Systems, Diabetes Management, (CGM).

I. INTRODUCTION

Continuous subcutaneous insulin infusion (CSII) was first introduced as a management strategy for both adult [1] and pediatric [2] patients with type 1 diabetes mellitus (T1DM) in the late 1970s. However, it was not until the Diabetes Control and Complications Trial [3,4] and epidemiology of Diabetes Interventions and Complications [5] studies confirmed and re-affirmed the pre-eminent role of glycemic control in the pathogenesis of microvascular complications that use of insulin pump therapy as "Intensive Therapy" in young people with diabetes has become increasingly widespread. Continuous subcutaneous insulin infusion (CSII) with a portable pump is an insulin therapy system first built in 1976 by Pickup and Keen for research purposes [1,6] At that time, the size of the pump was equal to that of a back bag. Nowadays, the size of an insulin pump is no bigger than a cell phone or a credit card. More than three lakhs patients around the world use a continuous subcutaneous insulin infusion (CSII) system today, and the number of "pumpers" is expected to increase dramatically in the next decade.[7]

The potential benefits of CSII became clear after the Diabetes Control and Complications Trial (DCCT) Research Group published a report in 1993.[8] Although the basic principles remain the same, several technological improvements have occurred in the previous 15 years, making insulin pumps safer, easier, and more flexible. Although CSII or pumps are the best method of insulin delivery for patients with type 1 diabetic and type 2 diabetic on MDI who are motivated, technologically savvy, and have the means to pay for the technology. [9]

II. INSULIN AND TYPE OF DIABETES

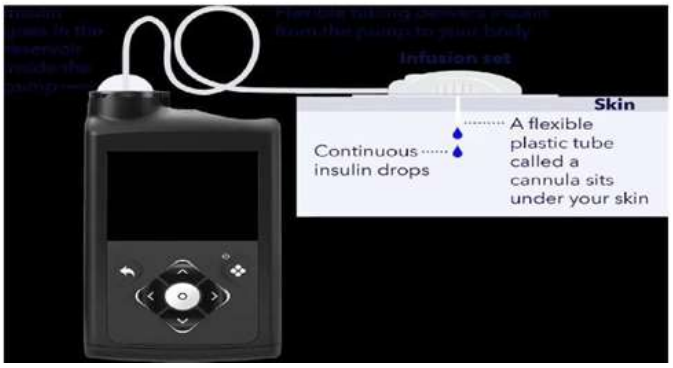
It is not absolutely necessary to know the type or pathogenetic origin of an individual's diabetes to manage their insulin therapy. This is because management, including choice of preparations used and insulin dose requirement, is in practice determined by glucose control as measured by self-monitoring. Indeed, particularly in the early years after diagnosis of type 2 diabetes, it can be unclear what type of diabetes is being managed (Table 1) [10] While specific tests, notably plasma C-peptide, can help, these have large ranges of uncertainty, while the auto- immune markers of type 1 diabetes can be positive in type 2 diabetes [11] and middle-aged people with abdominal obesity can develop T1DM. Much type 2 diabetes in thinner people beyond retirement age is unclassifiable.

What is often labelled as type 2 diabetes, including for clinical trial purposes, contains a rump of genetic syndromes previously known as maturity- onset diabetes of the young, while latent autoimmune diabetes of adults, generally sits with type 2 diabetes clinically but is a etiologically closer to type 1 diabetes.[12] In general, many types of maturity-onset diabetes

of the young respond well to sulfonylureas,[13] so in the past, before sulfonylureas became unfashionable, the need for insulin was simply determined by glucose control, even in the absence of specific diagnosis. An issue can arise, however, with genetic syndromes if diabetes is diagnosed in child hood, perhaps at a time of metabolic stress causing glucose levels to rise markedly, whence the pediatric diabetes team may conservatively assume T1DM, and start insulin with a plan for reviewing that need. This also occurs with neonatal diabetes, and, very rarely days, where glucosuria is mis confirmed as diabetes. To repeat, in many individuals the certain classification of the dis ease does not per se affect insulin management.

However, clear understanding can be important to people living with diabetes. Notably of course if this is T1DM, or diabetes secondary to pancreatic dis ease, then uninterrupted insulin dosing will be required for life (together with reassurance as to how this can deliver a long and healthy life). In these people the limitations of insulin therapy also mean that they are hypoglycemia prone—again it is useful to know that is usual. But similarly when starting insulin in people with T2DM in ambulatory care (as opposed to stress environments such as in patients), and including those with possible latent auto-immune diabetes of adults, the point should be honestly made that this is for life, that it will benefit future health, and that doses and types of insulin will change over the years.19 It is also important to communicate early on, particularly for the majority with abdominal obesity started on a basal insulin, that hypoglycemia is possible but unlikely

III. OPERATING INSULIN PUMP



When pump is on, it will show various icons. First, it will show a countdown, after which the screen goes dark, and then the version of the particular pump will appear on the screen. Then, a dark circle, a battery sign, and a syringe sign will appear on the screen. Generally, the battery work up to 10-12 days, and if there is a low battery alarm, then the battery should be immediately changed; some patient are commonly doing mistake in operating insulin pump by proper way; therefore, before starting pump therapy, patient or parents has understand the basic operating of pump [14]

IV. PROPER SELECTION OF SITE AND ROTATION

Patients need to change the infusion set site every 2-3 days and should always rotate to a new site. Some pump users may need to change the site more often if they notice their blood glucose is less stable over time. The abdominal area is the most common site for set insertions. The abdomen allows for more rapid and consistent insulin absorption than from other sites, especially after exercise. When using the abdomen, help the pumper to identify a variety of abdominal sites for adequate rotation. Imagining a clock drawn on the abdomen cane helpful. Ask the patient to rotate the site in clockwise position from 12 o'clock to 3 o'clock and so on, and make sure the site is convenient to insert the cannula. Some pumpers use the thigh or hip area; it is also possible to use areas higher on the abdomen that may have previously been used with injected insulin. Many prefer the hip area because it is "out of sight." If these sites are used, make sure that cannula placement is subcutaneous, not intramuscular. Make sure that your patients understand that the insulin pump will alarm only if insulin delivery is interrupted. Reinforce that the pump cannot detect and will not alarm for certain problems at the infusion site. Explain that occasionally infusion site may temporarily cease to absorb insulin properly, resulting in hyperglycemia.

V. CONSIDERATION OF CANDIDATES INSULIN PUMPS THERAPY

Patients should be considered for insulin pump therapy when intermittent insulin injections are not meeting treatment goals and outcome measures are sub-optimal, including, but not limited to:[15]

- A1C > 7.0-7.5%, accompanied by frequent severe hypoglycemia (70 mg/dL)
- Hypoglycemic events requiring third party assistance or interfering with work, school, or family obligations Frequent and unpredictable fluctuations in blood glucose levels
- Patient perception that diabetes management impedes the pursuit of personal or professional goals Prospective pump users or their care givers must be able to change infusion sets, fill pump cartridges and program the pump, and must demonstrate willingness to collaborate with healthcare providers in achieving the goals of diabetes therapy.[11,12]

In general, patients likely to succeed on insulin pump therapy will have had sufficient education and support while using other forms of insulin therapy so that they are already

competent in assessing the nutritional value of meals and monitoring blood glucose levels frequently (minimum four times a day, preferably 6-8 times) and checking ketone levels when appropriate.[16] Insulin pump therapy is contraindicated in patients lacking the commitment or competence to perform basic diabetes self-management behaviors;[6] however, many of recent research has shown that such patients can see positive results from using a pump.[11,14] Insulin pump users have the option of skipping or delaying meals and flexing the amount of carbohydrates consumed at one time. While taking insulin injections, patients must consume a pre-determined amount of food at specific times to prevent hypoglycemia from the onset and peak of the insulin injection [17] With a pump, mealtime insulin is delivered more based on the use of rapid acting insulin.

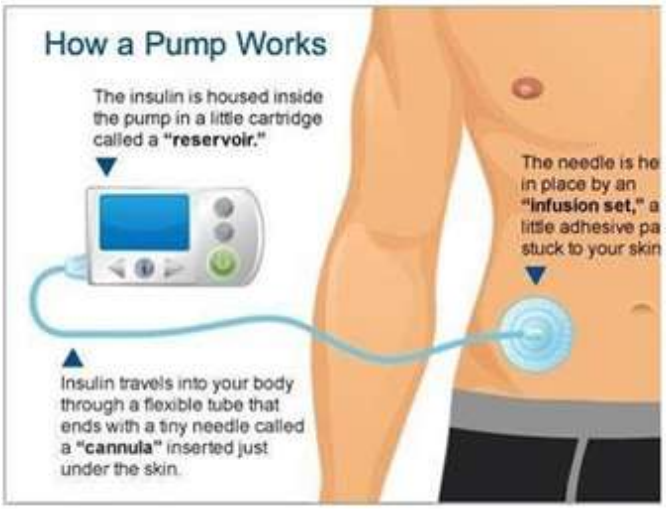


Fig.1 Working of insulin pump on patient body

VI. INDICATIONS FOR CONTINUOUS SUBCUTANEOUS INSULIN INFUSION

The National Institute for Health and Clinical Care Excellence (NICE) has published clear guidance on the use of continuous subcutaneous insulin infusion for adults with diabetes:

Technology Appraisal Guidance 151:

1. Continuous subcutaneous insulin infusion (CSII or 'insulin pump') therapy is recommended as a treatment option for adults and children 12 years and older with Type 1 diabetes mellitus provided that: Attempts to achieve target hemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycemia. For the purpose of this guidance, disabling hypoglycemia is defined as the repeated and unpredictable occurrence of hypoglycemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life [19] or HbA1c levels have remained high (that is, at 69 mmol/mol (8.5%) or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.
2. It is recommended that CSII therapy be initiated only by a trained specialist team, which should normally be comprised of a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian. Specialist teams should provide structured education programs and advice on diet, lifestyle and exercise appropriate for people using CSII.
3. Following initiation in adults and children 12 years and older, CSII therapy should only be continued if it results in a sustained improvement in glycemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the frequency and severity of hypoglycemic episodes. Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carrier.
4. CSII therapy is not recommended for the treatment of people with Type 2 diabetes mellitus, at present. 08 High level of care, as described in NICE TA151 includes:

- A high degree of motivation, commitment and competence;
- Estimating CHO consumption throughout every day
- Delivering multiple daily injections of insulin
- Regular glucose self-monitoring (≥4 times /per day) NICE also recommends insulin pump therapy for use in pregnancy (NG3) and in the management of diabetic gastroparesis (NG17) (Sharma et al. 2011).

VII. OTHER INDICATIONS

Other indications for pump therapy, with anecdotal evidence of benefit are:

- Diabetic neuropathy, painful peripheral and autonomic with orthostatic hypotension (Boulton et al. 1982)
- Insulin allergy (Pratt E et al. 2001)
- Needle phobia
- Type 2 diabetes with high insulin requirements who are not achieving optimal glucose control despite insulin doses titrated to over 1.0 units / kg (Aronson et al. 2014) CLINICAL GUIDELINE

VIII. ADVANTAGES AND DISADVANTAGES OF CSII

When offering CSII therapy it is important that consideration is given to the advantages and disadvantages as highlighted in table 1 (adapted from Hussain & Oliver: Insulin Pumps and Continuous Glucose Monitoring Made Easy, 1e, 2016, Elsevier Ltd) [20] Advantages of Pumps Over Metered Dose Inhaler (MDI) Fewer needle injections

- No need to inject every time insulin delivery is required Insulin delivery can be conveniently varied so allowing more flexibility
- Basal rates can be varied and programmed to match activity, shift work, changing requirements (e.g. pregnancy, hormonal changes, growth spurts, illness, travelling)
- Bolus can be delivered over a varied time to help with other conditions e.g. malabsorption, gastroparesis or dealing with particular foods e.g. pizza
- Temporary suspension or reduction of insulin delivery (activity and hypoglycemia)
- Allows pre-programming of insulin to deliver variable amounts insulin without constant input (e.g. whilst asleep or working)
- The greater flexibility in insulin delivery and reduced variability in glucose levels can enhance quality of life small insulin doses
- Deliver tiny doses (0.05-0.1 units) versus 0.5 -1 units from an insulin pen/syringe (useful for insulin-sensitive and young people) Overcome variations in insulin absorption
- Long-acting insulin can be absorbed differently in different people. Delivering programmed basal rates tailored to individual needs may overcome this problem, with the low volume of rapid acting insulin at the infusion site resulting in a more consistent, reliable insulin absorption and hence circulating insulin profile (Bruntomessoetal2008) Less snacks
- Tailored insulin delivery and reductions in insulin delivery during activity reduces the need for snacking I Improved patient experience and satisfaction

Improved self-management

- Technology can motivate and improve engagement better integration with technology
- Newer pumps can link with other technology such as meters, continuous glucose monitors, bolus advisors and diabetes information management systems

IX. DISADVANTAGES OF PUMPS OVER METERED DOSE INHALER (MDI)

Constant attachment to pump

- Must be worn all the time, including when asleep
- Constant visibility and reminder of diabetes
- Can affect perceived body image No long-acting insulin depot
- Risk of rapid diabetic ketoacidosis development if technical failure or interruption in pump insulin delivery
- Pumps should only be disconnected for short periods (eg swimming) Complicated set up - infusion set changes
- Set changes are complicated compared to injections and infusion sets and cannulas need to be changed every 2-3 days Infusion site problems
- Uncommon but risk of skin infection Infusion set problems
- Improper priming, air bubbles, tubing breaks and cannula kinks or slippages can interrupt delivery of insulin Increased education and training needed
- Requires higher level of education, understanding and motivation to get best use of pump and avoid problems Increased health care provider training needed
- Health care providers need to have adequate knowledge and clinical systems in place to support pump therapy Expense
- Pump costs as well as running costs (infusion sets, cannulas, batteries, accessories) are significantly more expensive than standard injections

X. COMPLICATIONS OF CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII)

User feedback on CSII has revealed some useful insights. In a survey of 92 insulin pump users with median duration of 3.3 years of CSII the following complications were described (Pickup at al. 2014) [23]

- Infusion set kinking 64%, 12% frequent*
- Infusion set blockage 54%, 10% frequent*
- Lipohypertrophy 26%
- Site infection 17%
- 48% reported any pump malfunction, with 26% reporting a pump stop/no delivery

*frequent = > 5/year or > 10 for duration of CSII (median 3.3 years)

Any pump malfunction which results in hyperglycemia carries a risk of metabolic decompensation. The pump only contains rapid acting insulin and if delivery is interrupted for any reason, hyperglycemia will result. If this is not detected and acted on appropriately then ketosis progressing to DKA will results.

Pump failure rates of 16-17 per 100 patient years have been reported, with just under 10% resulting in hospital admission due to metabolic decompensation (Ross et al 2016). Accidental damage to pumps accounted for just under 30% of pump failures. The median pump 'life expectancy' is just under 3 years (Rabbone et al 2017). An ADA/EASD diabetes technology working group have made a statement on the safety of insulin pump therapy with recommendations for increasing safety (Heinemann et al 2015).

XI. REASONS FOR CSII DISCONTINUATION

In the T1D Exchange registry 3% of pump users discontinued CSII within a year (Wong et al 2017). The reasons for discontinuation were: [24]

- Problems with insertion/adhesive 60%
- Pump interfered with sports activities 42%
- Pump uncomfortable to wear 38%
- Pump interfered with intimacy 34%
- Problems with pump working properly 28%
- Problems with high blood glucose levels when using pump 28% Data from a large UK pump service suggested that pump therapy was discontinued in 5% of users either due to lack of clinical benefit, technical issues, safety concerns or user choice (Beato-Vibora et al 2015)

XII. CONCLUSION

There is no one-size-fits-all approach to insulin pump therapy, and fortunately, there are many options for clinicians to consider with each patient with diabetes. Insulin pump technologies are advancing at an extraordinary rate and have potential to improve diabetes outcomes for individuals of all ages with type 1 or type 2 diabetes. However, individuals with diabetes must be able to overcome any barriers to device wear, have realistic expectations of their particular device, perform self-care, and complete extensive education and clinical follow-up to realize success with insulin pump therapies. It is important for clinicians to work with individuals with diabetes and their caregivers to optimize use of insulin pump technologies initially.

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