



Experience of using insulin pump therapy in underprivileged children from LMIC countries

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Abstract

Type 1 diabetes is increasing exponentially in India causing huge medical, financial, and social burden to children and their families. Providing basal bolus insulins, glucometers, glucose strips, and dedicated support by itself is a huge challenge to underprivileged children with type 1 diabetes in India. Advanced technologies that benefit the socially and financially disadvantaged children is still a distant dream in India and LMIC. We present our experience of initiating 200 insulin pumps to the most deserving underprivileged children with type 1 diabetes across Tamilnadu State with major indications for pump therapy. The nuances of patient selection, education, funding, setting up basal, and bolus rates along with trouble shooting tips to this group of children has been shared with the hope of replicating this model across India and LMIC countries. An out-of-box approach with Public-NGO-Industry is the way forward to ensure advanced diabetes technologies reach the unreachable.

Keywords Type 1 Diabetes · LMIC · Insulin pump therapy

Background

Type 1 diabetes is exponentially increasing worldwide with an estimated 8.4 million individuals as of 2021 [1]. The largest relative increase by 2040, predicted to be 60–107% of 2021 numbers, is expected to be in lower and lower-middle income countries. The prevalence of type 1 diabetes < 20 years of age in India (2021) is estimated to be 56.9/100,000 population with 50% of individuals receiving only “minimal care” as defined by a simple insulin regime, no or minimal self-monitoring of glucoses, HbA1c, or diabetes education [2]. Not surprisingly, this translates to huge medical, economic, and social burden, especially to rural deserving families [3]. While providing “minimal care” itself is such a huge challenge in LMIC countries, enabling advanced diabetes technologies like insulin pumps for the most deserving children is a distant dream. Insulin pump therapy is vastly under-utilized in a country like India, even for those who can afford the costs. These factors include lack of awareness about CSII therapy (Continuous Subcutaneous Insulin Infusion) among a large majority of doctors dealing

with diabetes, definite increase in short-term costs, patient preferences, and financial implications of purchasing insulin pump consumables for the long-term and the 24/7 support needed to sustain insulin pump therapy. However, there is accumulating evidence for the role of CSII in indicated patients with respect to improving quality of life [4], reducing clinically relevant recurrent and severe hypoglycemia [5], significant reductions in glycosylated hemoglobin [6], reductions in hospital admission with diabetic ketoacidosis [7], reductions in both micro and macrovascular outcomes [8, 9], improved cost-effectiveness, and quality of life [10, 11]. Idhayangal Charitable Trust, based at Coimbatore currently supports 2200 deserving children with type 1 diabetes across Tamilnadu with analogue insulins, glucometers, glucose strips, ultrafine needles, and insulin pumps. With 200 insulin pump deployments in the most deserving group of children supported with published work [12–14], we have accrued reasonable experience to pen our thoughts to be used as a general guidance for all healthcare professionals interested in insulin pump therapy in LMIC countries.

Our experience will cover the following headings:

1. Patient selection
2. Pre-pump counseling and education
3. Financial implications for pump therapy
4. 2-Week sensor augmentation: Coimbatore Model

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5. Fixing doses: total daily dose, basal, and bolus

- 5.1 Pitfalls in dose fixation in pump starts
- 5.2 Calculation of Starting Total Daily Dose for Insulin pumps
- 5.3 Total daily basal and bolus dose calculations from TDD pump dose
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- 5.7 The First 2 weeks of hand-holding: Bolus & Basal corrections
- 5.8 Basal dose adjustments
- 5.9 ICR

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7. Summary and conclusions

Patient selection: the AD concept

The most important determinant of success for insulin pump therapy is careful patient selection. The poverty or (il)literacy is not a determinant for rejecting pump therapy. The two most important attributes for a successful pump therapy are attitude and discipline (AD concept). Excellent assessment by the clinician is the key. Children who show a very keen interest will be selected for the pilot trial with no prejudice. Candidates for pump therapy are similar to international guidelines with a few special pointers in underprivileged children. Our indications are as follows:

- i. Children with brittle diabetes with huge fluctuations of glucoses despite best efforts with MDI (multiple daily insulin injections) for 6 months or more
- ii. Persistently high HbA1c > 8.5% despite best efforts of child and family with MDI and diet
- iii. Recurrent severe unpredictable hypoglycemias and hypoglycemic unawareness
- iv. Renal impairment or awaiting Kidney or SPK transplants
- v. Planning pregnancy with baseline HbA1c > 7.5% on MDI despite best efforts
- vi. Girls over 15 years *

*Girls from deserving areas are hugely discriminated especially when it comes to education or marriage; pump start on interested candidates over 15 years of age hugely improves their confidence & enables productive lives.

Pre-pump counseling and education

This is the most important predictor of pump therapy success in the long term. Our children have extensive counseling prior to pump start through the dedicated insulin pump educators. It is vital to have an experienced team of diabetes and specialist insulin pump educators along with peer-group interaction before pump starts. General suggestions before insulin pump initiation are as follows:

- Showing no prejudice, our best candidates on insulin pumps come from the most challenging socioeconomic circumstances.
- 3 E's: education, education, education is the key; careful patient selection is vital
- 24/7 Telephone support is mandatory, dedicated pump expert/educator essential
- Ensure adequate funding through NGO or Charitable sources at least for Year 1
- Go for the base model pump, financially viable and easy to understand.
- Mobile phone with WhatsApp key element for success, purchase one for the family if needed
- 2-Week trial before any promises
- Child safety is absolute; if even minor lingering doubts, do not go for the therapy. Do no harm, then think about doing good
- Make parents aware about the cost of the therapy so that they feel responsible for the success. Ensure one parent or sibling takes absolute responsibility

Financial implications for pump therapy

No insulin pump program can sustain without adequate funding, especially on a model that needs sustained recurrent support until such time the family is able to fund the therapy. On an average, capital costs of base model pump could be anywhere around Rs 2.25 lacs (\$2700) with monthly expenses for reservoirs, quicksets, and insulins around Rs10,000 per month (\$120). This is outside the reach of all our deserving families. Therefore, it is imperative that the team has adequate funding for at least 1–2 years for pump, consumables, and insulins. In our experience, significant reductions in hospital admissions, improvement of child's health and less time off work for parents will enable them to take care of at least a part of the expenses after a 2-year period. Our insulin pump program supporting 200 deserving children on insulin pumps is possible due to the unrestricted support from Idhayangal Charitable Trust (www.idhayangal.org), a registered charitable trust dedicated for underprivileged children with type 1 diabetes.

The 2-week sensor augmentation protocol: Coimbatore model

The first week of pump start demands the utmost time and follow-up, especially for rural families. A 1-h educational session with the experts gives a platform for the children and their families to get comfortable with the pump start. Children and families are taught about various components of insulin pump therapy including the bolus, basal and suspend buttons, priming the pump, filling the insulin reservoir, indicators on pump especially the battery and insulins icons, the importance of time as basal settings are time-dependent, changing batteries, the infusion set, and the arrow locks. A demo pump is used for children to get comfortable pressing various buttons and get ready for the pump start. Basal and bolus settings are determined for each child as per protocol in the next few sections of this paper. The Lead Consultant will finally go through all the settings and “test” the children on their understanding of the pump. We refrain from in-patient admissions for pump starts; children from long distances stay in Coimbatore courtesy of Idhayangal Trust for 2 days till the first set change. Since we have children all over the State on insulin pumps, the new children are connected to their peers locally for trouble shooting and first few set changes. Our personal experience suggests that the first 2 weeks of insulin pump therapy is augmented by some form of continuous glucose monitoring other than finger-prick glucoses, as we expect at least seven to eight recordings per day. However, sensor augmentation continuously with the supplier’s sensor is beyond the reach of even the richest trust’s financial capability. Our model negates this by inserting the Free style libre sensor for 14 days. Children are given the reader along with the sensor for the first 2 weeks of pump start so that they can send the data through WhatsApp without the need to do multiple finger-pricks. Most of our children settle to a good glycemic control within 3–4 days of therapy. After the first 2 weeks, the readers are returned so that next group of children can be started on the pump. Children return to finger prick testing at least three to four times per day after the first 2 weeks. Each child receives 90 capillary glucose test strips free of cost along with insulins for the month. The consumables and insulins are not extended without the following: At the minimum three capillary glucose checks per day that is communicated to the team through Apps, a personal phone call at least once a week from the child’s family updating on the status and a mandatory 3-month follow-up with the Lead Consultant along with HbA1c and appropriate blood tests. All the children should bring with them the glucometer (given free of cost) with the memory revisited to crosscheck all their noted results.

Fixing doses: total daily dose (TDD), basal, and boluses

Once the funding is sorted, pump education given, and ambulatory glucose sensor inserted; next in line is fixing the TDD on pump, the basal rates, and bolus rates. There are many pitfalls that can lead to potential morbidity during pump starts if standard protocols based on Western practices or manufacturer’s recommendations are carried out. These are due to certain LMIC specific issues outlined below.

Pitfalls in dose fixation in pump starts

- Refrain from TDD on previous MDI based dosing due to the following factors; most children use insulins of poor potency due to lack of fridge, poor storage, poor insulin techniques, and insulin lipohypertrophy. Use of TDD-based insulin dosing leads to severe hypoglycemia once absorption of insulins is much better on CSII. It is not uncommon to find such children on 80–100 units of insulin on MDI needing only 30–40 units on CSII. Use weight-based dosing in these socioeconomic strata
- Avoid standard basal settings for 24 h in this population as insulin requirements vary at different times. We use the Rule of Five basal settings, i.e., five basal rates split over 24 h; more details are shown below

Calculation of starting total daily dose for insulin pumps

Use weight-based dose as suggested *. Our thumb rules based on clinical experience are as follows:

Age < 12 years: 0.5–0.7 units/ kg/day

Age > 12 years: 0.7–1 unit/ kg per day

For example, if we have an 8-year-old child weighing 30 kgs, a reasonable starting dose on pump would be as follows:

$$30 \times 0.6 = 18 \text{ units TDD}$$

If a 14-year-old is going through puberty weighing 60 kgs, a reasonable starting dose on pump would be as follows:

$$60 \times 0.8 = 48 \text{ units TDD}$$

*Always go low and slow; the aim is to ensure no severe hypoglycemia and confidence in pump therapy rather than perfect control within 2 days of pump start. If a child is less than the 75th centile on weight chart for age, use the lower end (0.5 units/kg if < 12 years and 0.7 units/kg if more than

12 years; if > 75th centile on weight for age chart, use the higher range for TDD). If there is history of recurrent severe hypoglycemia, go for the lower range of starting doses. These are guestimates; use clinical judgment all the time.

Total daily basal and bolus dose calculations from TDD pump dose

First determine the percent of insulin to be delivered as basal insulin, and then multiply the TDD by that percent. This will give you the Total Daily Basal amount. To calculate the Total Daily Bolus amount, subtract the Total Daily Basal amount from the TDD.

For example, if you have a pre-pubertal child needing TDD on insulin pump of 24 units, the total daily basal rate will be $24 \times 0.5 = 12$ units, the total daily bolus will be TDD- Total daily basal rate = $24 - 12 = 12$ units, and the bolus can be split to 4 units with each meal.

For example, if you have a child going through puberty needing TDD on insulin pump of 50 units, the Total daily basal rate will be $50 \times 0.4 = 20$ units, the total daily bolus rate will be TDD-Total daily basal rate = $50 - 20 = 30$ units, and the bolus can be split to 10 units with each meal.

Suggestions for Total Daily basal and bolus percentages

	Basal	Bolus
Pre-puberty to Puberty	50 %	50 %
Puberty to adult	30-40 %	60%-70%
Adult	50%	50%

Setting up of basal rates

Once the total daily basal rates are arrived, we use the Rule of Five to set the basal rates [10]. Our experience shows a smooth control of glycemia within a week of pump start with the Rule of Five rather than the standard basal rate starts for 24 h. Try not to have too many peaks and valleys in the basal program. It is better to have one peak and one valley rather than multiple peaks and valleys. Our aim is to mimic the basal insulin secretion by the pancreas as close as possible. An example of basal setting based on our published work for someone needing a total basal dose of 21 units would be as follows:

12 – am, 0.75
 4 – 8 am, 0.85
 8 – 1 pm, 1.0
 1 – 8 pm, 0.9
 8 pm – 12MN, 0.8

Suggested tips for bolus dosing among deserving children

Unlike Western countries, we do not suggest carbohydrate counting as the first step for setting bolus rates among our group of children nor do we suggest using bolus wizard as an initial step. There are many reasons including varied food pattern in India where carbohydrate content varies for the same food in different places and different socioeconomic strata; lack of standard CHO counts for food consumed in such strata of society and to avoid a feeling that pump therapy is very complicated. We therefore split the total bolus dose per day into three for each main meal and use a guestimated snack bolus; check 1 h and 2 h PP glucose after meals/snacks, and titrate the dose of bolus insulins. For example, for the child needing 21 units as basal with a TDD of 45 units, the Total bolus requirement for a day is TDD – Total daily basal = $45 - 21 = 24$ units; this will be split into eight units with each meal for a start and dose titrated depending the PP glucose levels.

Insulin sensitivity factor (ISF) and correctional bolus calculations

ISF is calculated by the team and used for correctional boluses given as a standard chart for the families. Children can get confused by such terminologies. Education about ISF is imparted to the child and family only when stable glycemia is achieved and child is confident of the therapy.

ISF is defined as the number of mgs/dl of glucose lowered by 1 unit of insulin

If child has recurrent hypos or insulin sensitive, use the 2000 rule; otherwise, use the 1800 rule.

For example, if a child is on TDD of 45 units and otherwise stable, the ISF is calculated as follows:

$1800/45 = 40$ mgs/dl; therefore, one unit of insulin will lower the glucose by approximately 40 mgs/dl. This will be used for correctional bolus or additional boluses if glucoses more than the set targets.

The first 2 weeks of hand-holding: bolus & basal corrections

The first 14 days of pump therapy are extremely crucial for the success of therapy. The 24/7 telephone support is vital as minor errors can potentially lead to major morbidity and

mortality. All our pump children have phone numbers of the entire team from the pump educator, doctor, and the diabetes specialist nurse. While most of the communication is through WhatsApp, children and their families should feel comfortable calling anytime if needed. After the first 2 weeks, most of our children are comfortable with giving boluses based on their meals and glucoses.

- Every pre-meal, pre-snack, 1 AM, and 4 AM glucose trends on AGP should be photographed and sent to the team
- Alarms are set at 1 am and 4 am for the first 2 weeks for children to send data to the team to finetune basal rates
- Any glucoses < 70 mg/dl or > 300 mg/dl should be reported immediately to the team through phone call instead of WhatsApp.

Basal dose adjustments

Our rule is as follows for pump starts in this cohort of children, “Bolus button is for child’s family and basal setting is for the Pump Team.” Refrain from teaching or adjusting basal rates initially for child’s families as we see a lot of trouble shooting due to “erroneous button pressing” or “playing” with the pump settings. All we teach is how to press the bolus button and how to use the Suspend button; talking or teaching about other pump settings like basal initially will lead to more confusion. However, once stable glycemia is reached, and we feel that the child’s family is understanding the pump, then all the above are gradually taught. All children at 6 months of pump therapy undergo an advanced training module with the pump.

Fix the fasting first (FFF concept)

Assess overnight control by assessing patterns of glycemia on AGP, e.g., bedtime to 12 midnight, 12 MN–4 AM, and 4 AM–7 AM. Adjust basal insulins to match diurnal variations.

Goals: BG variations are < 50 mg/dl.

- If BG rises or falls > 50 mg/dl, adjust basal rates by 10–20% 2 h before the expected rise or fall
- If BG goes < 70 mg/dl, treat the hypo and decrease rate by 20%

Day time basal rates adjustments: fasting method

Evaluate BGs across skipped meal time segments (preBF–prelunch, pre-lunch–pre-dinner, pre-dinner to bedtime). Adjust basal rates based on rise/fall patterns across skipped meal times.

- If BG rises or falls > 50 mg/dl, adjust rate 10–20% 2 h before the expected rise or fall
- If BG drops to < 70 mg/dl, treat hypo and decrease rate by 20% 2 h before the hypo

ICR (insulin carbohydrate ratio)

Once children and family are comfortable with the pump, concepts ICR are slowly introduced. On an average, we introduce the ICR concepts three months after the pump start and stable glycemia achieved. Insulin-carbohydrate ratio (ICR) is the number of carbohydrate grams covered by one unit of insulin.

The 500-rule is an easy starting point for ICR calculation: $ICR = 500/TDD$

For example, if the child is on 50 units of insulin total daily dose, then the ICR is $500/50 = 10$, i.e., 10 gms of CHO is covered by one unit of insulin. Indian-specific food charts are given to the children’s family to enable them to count the ICR and give boluses in a more scientific way once the families understand the concepts.

Trouble shooting tips

Insulin pump initiation in underprivileged children is the easiest of the lot; however, hand holding, sustainability, and troubles shooting 24/7 are the primary challenges, especially in children from far-off remote areas. This requires a very dedicated team known to the children’s families, who are available at the other end of the phone anytime day or night. We do not rely on the pump providers helpline for this category of children due to various reasons including lack of personalized touch, difficulty in access and understanding to name a few. These are the common trouble shooting issues we see in day-to-day practice.

Insulin pump occlusions or interruptions

This is a huge concern that merits extensive counseling for children and families before after pump starts. There are various ways in which insulin flow can be blocked including kinking of the cannula, displacement of the cannula, or compression of the cannula. Many deserving children sleep on the hard floor, and such kind of occlusions can happen when the child tosses around during sleep. Sudden interruptions of insulin flow can result in severe hyperglycemia within hours and huge risk for diabetic ketoacidosis. The

following checklists below help in preventing unnecessary admissions due to insulin pump issues.

- Always change the infusion set on the 3rd or 4th day; prolonged use of the canula may increase the risk of occlusion
- Do not change the infusion sets before going to bed; any occlusions or interruptions to insulin supply may go undetected during sleep with a high risk of diabetic ketoacidosis by morning. Always do the “set change” first thing in the morning or before 5 pm in the evening so that any sudden hyperglycemia can be picked up and treated before bed time
- If on sensors, always keep track of the BG values 1 h, 2 h, and 4 h after the “set change.” Like take-off and landings, the most critical period in insulin pump therapy is immediately after the infusion set change as occlusions can happen during this time if the cannula is not properly inserted. If the child is using glucometers, request glucometer values 1 h after set change before going to school or before bed time if the infusion set was changed in the evening
- Any glucose value > 300 mgs/dl especially on the day of set change without an obvious cause, e.g., missed bolus or low bolus doses for a given snack or 2 consecutive high BGs in a row or high glucoses despite giving correctional bolus through pump, it is extremely likely that this is due to infusion set kinking or occlusion; **DO NOT GIVE BOLUS DOSES ON PUMP**; request child’s family to contact the team immediately
- Mandatory to always have a fast-acting insulin vial or pen on standby or at least a 100-unit insulin syringe to cover for any pump occlusions or failure. The child’s family should be aware to give bolus dose of fast acting insulin subcutaneously if glucoses high and call the team immediately. The 100-unit insulin syringe can be used to draw insulin from analogue cartridges given to children if they do not have a standby fast acting insulin pen
- Any travel outside, child’s family should have back up fast-acting insulin and needles/ syringes, list of phone numbers, and additional pump consumables and sertes. Any issues with the pump anywhere can be immediately managed with fast acting s/c insulin or mix insulin till such time help arrives
- List of all phone numbers to contact the team in case of emergency should be stuck on the front door of the fridge; parents should be advised to carry the list with them all times in case of emergency; nothing beats a phone call to the team as many serious morbidity and mortality can be prevented by a simple phone call. Any nausea, vomiting, and intercurrent illness should be immediately brought to the attention of the pump team, more frequent glucose checking, e.g., 1–2 h, ketone testing; if possible, correctional boluses and adequate hydration can prevent major admissions; however, any worrying signs would need immediate hospitalization
- Educate the families for obsessive need of ensuring that the arrow mark on the patch is aligned; any small deviation can lead to interruption of insulin supply
- Pump discipline mandatory; close SMBG (self-monitoring of blood glucose) or ambulatory glucose profiles compulsory; taking the eye from glucose levels especially on day of set change can be potentially dangerous. All pumps among deserving are base model pumps without continuous sensor augmentation from manufacturer’s devices; one must rely on SMBG or flash glucose monitoring
- Any hypoglycemia should be dealt first by suspending the pump followed by carbohydrates; many families forget to suspend the pump leading to persistent hypoglycemia
- Counsel children and families that the insulin pump is not a play toy to be messed with or share with friends; child lock features should be explained clearly to parents so that the child cannot over bolus insulins; set max bolus and basal rates so that even inadvertent or unnecessary attempts at overbolusing can be avoided
- Skin infections and allergies are uncommon if standard aseptic protocols are followed. Rare instances of allergy and redness to the patch have been observed
- Any lack of pump discipline despite repeated warnings should lead to a very low threshold of removing the pump and back to subcutaneous basal bolus insulins

Summary

Insulin pump therapy is a life-transforming option in indicated children with Type 1 diabetes. Some quotes from our patient’s perspectives are as follows: “My best friend, my Insulin pump,” “A second life,” and “I could not have had my daughter without my insulin pump.” With such perspectives, poverty, socio-economic strata, and literacy should not be contra-indications for pump therapy for deserving children desperately needing such treatment. A dedicated team with private-NGO-Industry partnership can overcome many of the hurdles associated with the financial aspects of pump therapy. There are unique considerations in the medical aspects of insulin pump therapy among deserving children in LMIC countries that has been outlined in the document. This template can be used as a platform to ensure that technologies such as insulin pump therapy reach the most deserving sections of our society safely to enable them to lead happy healthy productive lives.

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