

One-Year follow-up of 50 Rural Underprivileged Type 1 Diabetes Children on Insulin Pump Therapy: Breaking Socio-Economic Barriers in Diabetes Technologies

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Abstract

Aims: To audit the feasibility and clinical outcomes of fifty rural underprivileged children with Type 1 diabetes on insulin pump therapy for a one-year duration. **Material and Methods:** All patients were audited from the Type 1 database of Madhuram Diabetes and Thyroid Centre (Unit of Idhayangal Charitable Trust www.idhayangal.org, NGO focussed on Type 1 diabetes from poor socio-economic strata). Below Poverty Line (BPL) was defined as any family earning less than Rs 2 lacs per annum. All children acted as their own controls managed on MDI for at least six months before pump start. Data were tabulated in Microsoft Excel and analysed. **Results:** There were significant reductions in glycosylated haemoglobin at 6 months and one-year of insulin pump therapy compared to baseline pre-pump MDI values. In addition, significant reductions in diabetic ketoacidosis and severe hypoglycaemia admissions were seen. **Conclusion:** Insulin pump therapy without prejudice on indicated well-selected rural underprivileged children with Type 1 diabetes leads to clinically meaningful outcomes. NGO-Private-Industry partnership is vital to expand access of modern diabetes technologies to reach the most underprivileged.

Keywords: Insulin pump, Poor socio-economic strata, Type 1 diabetes

BACKGROUND

Type 1 diabetes is increasing exponentially in India with an (under) estimated 128500 children and adolescents with Type 1 diabetes.^[1] Significant numbers of such children are from rural underprivileged families. Continuous subcutaneous insulin infusion (CSII) is a very effective way of insulin delivery in highly selected patients with Type 1 diabetes, with accumulating evidence for the role of CSII in improving quality of life,^[2] reducing clinically relevant recurrent and severe hypoglycaemias,^[3] significant reductions in glycosylated haemoglobin,^[4] reductions in hospital admission with diabetic ketoacidosis,^[5] reductions in both micro and macrovascular outcomes^[6,7], and improved cost-effectiveness.^[8] However, such technology is vastly under-utilised in a country like India due to a multitude of factors. These factors include lack of awareness about CSII therapy, definite increase in short-term costs, patient preferences, financial implications of purchasing insulin pump consumables for the long term, and the 24/7 support needed to sustain insulin pump therapy. There seems to be a resigned exasperation among medical

professionals with respect to Type 1 diabetes, especially in the rural underprivileged, as it means a lot of effort and consultation time to the extent that Type 1 diabetes especially among underprivileged children is aptly termed as the “poor cousin” of Type 2 diabetes. Our aim is to ensure that advanced diabetes technologies like insulin pump therapy should transcend socio-economic barriers for the benefit of deserving underprivileged children from rural India. Our pilot work on 16 underprivileged children with Type 1 diabetes on insulin pump therapy and setting up of basal rates has been previously published.^[9,10] This study presents the outcomes of one-year follow-up of 50 rural underprivileged children on insulin pump

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therapy through a NGO-Private-Industry partnership. We envisage this model to be the platform for enabling children from poor socio-economic strata to lead healthy productive lives through access to modern diabetes technologies.

AIM

To assess the feasibility, and one-year clinical outcomes on insulin pump therapy among 50 rural underprivileged children with Type 1 diabetes, previously on stable MDI therapy but suboptimal glycaemic control, for at least 6 months before the pump start.

MATERIALS AND METHODS

This study was a retrospective audit of all patients selected from the Type 1 database of Madhuram Diabetes and Thyroid Centre (Unit of Idhayangal Charitable Trust www.idhayangal.org, NGO focussed on Type 1 diabetes from poor socio-economic strata). Below Poverty Line (BPL) was defined as any family earning less than Rs 2 lacs per annum. Criteria for insulin pump therapy were used as per standard international guidelines. All children received insulin pumps and consumables free of cost through a joint partnership with Idhayangal Charitable Trust, a registered charity in India with a sole aim of supporting underprivileged patients with Type 1 diabetes, cost-price pump procurement through India Medtronic and Corporate Social Responsibility funding by private partners. The duration of study was for a period of one year (April 2020–April 2021).

All children were on multiple daily subcutaneous insulin (MDI) for at least 6 months before the pump start. Therefore, children acted as their own controls considering that the pre-pump HbA1c reflected the best glycosylated haemoglobin that could be achieved with maximum efforts on MDI for at least six months before the pump start. Two pump starts were scheduled for a week, so that enough time was available to concentrate on both the children, as the first week of pump start demands the utmost time and follow-up. A one-hour educational session with the experts gave a platform for the children and their families to get comfortable with the pump start. However, all these children were primed before the pump start either by visiting similar children in their local places or by educating them during each clinic visit three months before the initiation. We used only the Medtronic 715 or 722 pumps, which are base model pumps. Sensor augmentation continuously with the supplier's sensor was beyond the reach of the stakeholder's financial capability. We negated this by inserting the freestyle libre sensor for 14 days [Figure 1]. Most of our children settled to a good glycaemic control within 3–4 days of therapy. After the first 2 weeks, the readers were returned to the trust, so that two more children can be started on the pump. Children return to finger prick testing at least 3–4 times per day. Each child receives 90 capillary glucose test strips free of cost along with insulins for the month. 24/7 telephone support was provided with a mandatory three-month follow-up with

HbA1c and review by the lead consultant. Additionally, a free ambulatory glucose sensor was inserted every three months for the one-year period.

Demographic data and all other variables including age, sex, annual family income, pre-pump glycosylated haemoglobin, post-pump values, admissions with diabetic ketoacidosis and hypoglycaemias (both mild and severe hypoglycaemias) were recorded on Microsoft Excel and analysed for 12 months. Paired t-test was used to test the statistical significance between variables, and a *P* value of <0.05 was considered significant. The data collected was anonymized and no patient identifiable information was used.

RESULTS

A total of fifty children with Type 1 diabetes were started on continuous subcutaneous insulin infusion from rural BPL families. The mean age at diagnosis of Type 1 diabetes was 12.2 years (5.3), and the mean body mass index was 20.1 (3.5). The mean glycosylated haemoglobin at diagnosis was 12.4% (2.5) (112 mmol/mol). The pre-pump glycosylated haemoglobin after at least 6 months of stable MDI was 10.42% (90 mmol/mol). We showed a statistically significant reduction in glycosylated haemoglobin at the end of 3, 6, and 12 months of pump therapy, 8.2% (66 mmol/mol), 7.9% (63 mmol/mol), and 7.5% (58 mmol/mol), respectively. The total number of diabetic ketoacidosis admissions had reduced from 18 episodes the year preceding the insulin pump therapy to one episode for those who have completed one year of therapy ($P < 0.01$). Episodes of hypoglycaemias reduced from 282 episodes the year preceding the pump to 76 episodes for those who had completed one year of insulin pump therapy ($P = 0.01$). Severe hypoglycaemias, as defined as hypoglycaemia needing third party help or hospital admission, reduced from 28 episodes a year before pump start to two episodes after one year of pump therapy in this cohort [Table 1].

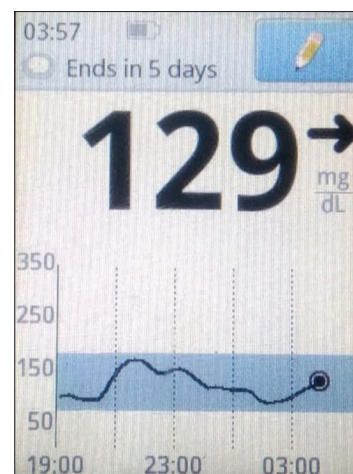


Figure 1: Poor man's sensor augmentation: 2 weeks of freestyle libre sensor with reader at insulin pump start enabling smooth dose adjustments and time-in-range within 3–4 days from any part of the state

DISCUSSION

Insulin pump therapy without prejudice in indicated rural underprivileged children with Type 1 diabetes is feasible and clinically meaningful with a NGO-Private-Industry partnership. Our study highlights significant sustained reductions in glycosylated haemoglobin at the end of one year of pump therapy compared to at least six months of stable MDI therapy with significant reductions in diabetic ketoacidosis and severe hypoglycaemia admissions.

There are common myths both among doctors and patients with respect to insulin pump therapy in India. Such myths include the notion that insulin pumps are not a great option in India, pumps do not work in hot weather, all insulin pump therapy should be sensor augmented that is beyond financial reach of most patients, insulin pumps are mainly for rich and literate patients, rural poor families will be unable to deal with technologies, and instead of one pump, ten children can be given MDI. Our study refutes every single myth outlined above and highlights new dimensions of pump therapy among the deserving poor. Insulin pump therapy is a viable option in these strata through dedicated efforts of NGOs, industry, and philanthropic institutions. Most of our children are from deep interior villages across Tamil Nadu state experiencing some of the hottest weather during summer, there is no pressing need for continuous sensor augmentation as we show good clinical outcomes with “poor man’s sensor augmentation”, that is 2 weeks of freestyle libre pro at pump start followed by 3–4 times finger prick glucose and ambulatory glucose every 3 months for 2 weeks. Our study also proves that rural underprivileged children can handle modern technologies as good if not better than their urban counterparts. The key to such outcomes is the efforts by the team to educate the children and their families along with 24/7 support. Finally, underprivileged children with screaming indications for insulin pump should not be discriminated just because this can fund more children on MDI, for that particular child, pump therapy would be life-saving and life-changing.

Our main strength of the study is the fact that all children acted as their own controls. All selected children had been on MDI for at least 6 months before pump start with the same efforts directed towards their diabetes education and glycaemic control. However, it is early days with the need for a long-term follow-up to see whether such clinical outcomes can be sustained. Long-term funding is also an issue; however, we have been successful in assigning local charities to support every child along with an aggressive campaign to rehabilitate families for sustainable livelihood as an exit strategy.

Table 1: Pre- and post-insulin pump differences

Variable	Pre-CSII	Post-CSII 1 year	P
HbA1c (%)	10.42	7.5	<0.01
Diabetic ketoacidosis	18	1	<0.01
Any hypoglycaemia	282	76	0.01
Severe hypoglycaemia	28	2	<0.01

CSII Continuous subcutaneous insulin infusion

In summary, our study has given us the confidence that insulin pump therapy without prejudice, for deserving children from rural underprivileged families, is feasible with a joint Private-NGO-industry partnership. Such therapy with a dedicated multi-disciplinary team leads to meaningful reductions in glycosylated haemoglobin, hospitalisations with diabetic ketoacidosis, and hypoglycaemias. Such reductions will hopefully be cost-effective as well in the long term for poor families in terms of complications and hospital admissions. Long-term follow-up of this cohort will be extremely helpful to inform Governmental Health Agencies in the subcontinent to adopt insulin pump therapy and modern diabetes technologies as a part of either Central Government or State Government schemes that would transform lives of underprivileged children and their families with Type 1 diabetes.

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Conflict of interest

Ithayangal Charitable Trust receives funding from various organisations including India Medtronic for philanthropic work.

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