Breaking Socioeconomic Barriers in Diabetes Technologies: Outcomes of a Pilot Insulin Pump Programme for the Underprivileged in Rural India

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Abstract

Aim: To assess whether the socioeconomic and stereotypical barriers for the adoption of advanced diabetes technologies can be overcome in the underprivileged children and their families in India, predominantly from the rural areas, by providing insulin pump therapy (CSII) to deserving patients. **Materials and Methods:** All patients were selected from the type 1 diabetes mellitus (T1DM) database of the Kovai Medical Center and Hospital, Coimbatore. Sixteen people with type 1 diabetes (PWD) were chosen due to poor control or an urgent situation like pregnancy or renal failure. Demographic data along with variables such as age, sex, time of diagnosis of T1DM, duration of CSII therapy, total daily insulin dose, hypoglycaemias, hospitalisations, glycosylated haemoglobin pre- and post-pump were collected. The glycosylated haemoglobin values were collected at 3, 6 and 12 months, post-CSII hypoglycaemia was defined as self-reported hypoglycaemia by the patient. **Results:** During 12 month follow-up, all 16 PWD were using the insulin pump with significant reductions in HbA1c from 11.4% at baseline to 8.0% ($P < 0.001$) and 7.6% at the end of 3 and 6 months, respectively. **Discussion:** Our results indicate that the CSII therapy without prejudice can lead to significant reductions in glycaemic control, hospitalisations and quality of life. This pilot work will help us lobby government policy makers to ensure policy changes that help the underprivileged with T1DM in India.

Keywords: CSII – continuous subcutaneous insulin infusion, MDI – multiple daily injections, PWD –people with type 1 diabetes

BACKGROUND

India has close to 100,000 children with type 1 diabetes and this number is rising by 3% per annum. The prevalence is much more than previously thought, ranging anywhere from 3.7/1,00,000 in Karnataka to 31.9/1, 00,000 in Haryana.[1–3] However, type 1 diabetes does not receive as much attention probably due to the sheer prevalence of type 2 diabetes in India. Hence, type 1 diabetes in India is often referred to as a 'poor cousin of type 2 diabetes'.[4] In addition, the enormous amount of professional and personal consultation time required to counsel children and their families may be perceived as a huge burden for healthcare professionals, who already have a busy general diabetes practice.

As in high income countries, children with type 1 diabetes have a higher mortality and morbidity than their non-diabetic peers.[5] There is only a limited data on the complications and mortality rates in patients with type 1 diabetes in India, but even scant evidence suggests that they are often high relative to well-resourced settings, with prevalence of retinopathy in adolescents varying from 18 to 47%.[6,7] Lack of resources is one of the principle causes for the poor outcome. Significant number of children with type 1 diabetes from our practice comes from poor families. For example, many of our children's parents earn <Rs 15,000 per month with the economic burden of the best insulins (analogues) and consumables costing nearly Rs 3500–4000/month. One hospital admission with a diabetic emergency costs around Rs 80,000 or more. Even access to simple insulin vials can be difficult in the rural areas catering

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to poor socioeconomic strata due to patchy governmental supplies of appropriate insulins. However, factors beyond resource availability limit access towards better diabetes care. Illiteracy, lack of awareness in families, societal taboos especially to girls with type 1 diabetes in India, poor awareness of nuances of type 1 diabetes among physicians in general and the ease of access to native treatment, all contribute to the alarming morbidity and mortality for children with type 1 diabetes, especially in rural India. Studies have shown that rural youth with type 1 diabetes even globally had higher rate of hospital admissions, lower appointment adherences and poorer communication with their care team compared to their urban counterparts.[8] We therefore set out to investigate whether children and their families from the poor economic background in rural India can cope with the perceived burden of insulin pump technology and thus challenge prevailing notions and prejudices.

AIM

To assess whether the socioeconomic and stereotypical barriers for the adoption of advanced diabetes technologies can be overcome in the underprivileged children and their families in India, predominantly from the rural areas, by providing insulin pump therapy (CSII) to deserving patients.

MATERIALS AND METHODS

All patients were selected from the type 1 diabetes database of the Kovai Medical Center and Hospital, Coimbatore. Type 1 diabetes was defined based on GAD antibody positivity or presentation with diabetic ketoacidosis (DKA) at admission <18 years of age or if a diagnosis of type 1 diabetes was made by the consultant endocrinologist. Patient selection criteria for initiating CSII were made at the discretion of the consultant endocrinologist based on the following: persistently high HbA1c >8.5% in spite of being on multiple daily injections (MDI) and a high level of care, recurrent unpredictable hypoglycaemias or hypoglycaemic unawareness, patients with advanced renal failure on dialysis awaiting transplant, pregnant women with type 1 diabetes. Patients were to be motivated to be on a pump, to have regular contacts with the diabetes team and with no obvious underlying psychiatric disorder. The socioeconomic criteria was that the family income to be <2 lac rupees/annum (USD 3000/annum), there were individual exemptions based on the family circumstances if earning more than the above. All had the inability to afford an insulin pump or consumables. All patients and their caregivers had a 2 week trial on the pump with extensive education and mobile texting of glucometer values at least five times a day for the first 2 weeks. A senior dietician well versed in carbohydrate counting counselled all patients with a modified Indian food carbohydrate counting chart available through India Medtronic. A 24/7 phone number manned in rotation by the diabetes care team was given to all our patients on pump.

Demographic data along with variables such as age, sex, time of diagnosis of type 1 diabetes, duration of CSII therapy, total daily dose (TDD) of insulin, hypoglycaemias, hospitalisations, glycosylated haemoglobin pre- and post-pump were collected. The glycosylated haemoglobin values were collected at 3, 6 and 12 months, post-CSII hypoglycaemia was defined as self-reported hypoglycaemia by the patient. Severe hypoglycaemia was defined as hypoglycaemia needing a third party or hospitalisation to recover. Quality of life (QoL) was assessed by a simple questionnaire coded by a Likert's scale (1–5), where 1 was coded as extremely poor and 5 as excellent. Individual free text comments were also collected based on patient's perception of life pre- and post-CSII.

Statistical analysis

Data were tabulated on Microsoft Excel. Data are presented as mean and standard deviation (SD). Paired *t*-test was performed to analyse statistical significance between the variables. A *P* value < 0.05 was considered significant.

RESULTS

Sixteen patients with type 1 diabetes were enrolled in this outreach programme for CSII among the lower socioeconomic strata. All patients had type 1 diabetes either based on GAD antibody or presentation with DKA at first diagnosis or had a diagnosis of type 1 diabetes made by an endocrinologist. The mean age of patients was 18.7 years (6.5) the youngest was 6 years and the oldest was 29 years at the time of CSII initiation. Thirteen of the 16 patients (81%) were in villages, 3 patients were from the rural outskirts of Coimbatore city. Nearly 40% of the patients were from the agricultural families in villages anywhere between 60 –300 km from our base hospital in Coimbatore city. The mean income was Rs 20,200 per month ($290/month) with 60% of patient's parents earning <Rs 15,000 per month ($220/month). Eight patients were on the MiniMed Paradigm 715, six were on the MiniMed Paradigm 722 and two patients were on the MiniMed Paradigm 754 (Veo) pump (Medtronic Inc., Northridge, CA).

The mean age at diagnosis of type 1 diabetes was 10.6 years (5.8) [Table 1], the mean duration of type 1 diabetes as of June 2018 was 97 months. The mean TDD of insulin pre-CSII was 47.5 units. The mean glycosylated haemoglobin (HbA1c) prior to CSII was 11.4%. The mean QoL score was 1.1 (from a scale of 1–5, 1 being very poor and 5 being excellent). The mean duration of CSII therapy was 20.1 months (14.6).

HbA1c at 3 months improved from mean of 11.4% at baseline to 8.0% (*P* < 0.001), this further reduced to 7.6% at the end of 6 months (*P* = 0.6) of CSII and maintained at this level at 12 months [Table 2]. The mean TDD of insulin reduced to 38.6 units from a pre-CSII mean of 47.5 units, however, this was not statistically significant (*P* = 0.16). The number of hospital admissions pre- and post-CSII were numerically lower (*P* = 0.09). There were no admissions related to DKA

Table 1: Baseline characteristics of CSII study population

Variable	Mean (SD)
Total (*n*)	16
Age (years) as of 2018	18.7 (6.5)
Age (years) at diagnosis of type 1 DM	10.6 (5.8)
Monthly income (rupees)	20,250 (11,186)
Duration of type 1 diabetes (years)	8.1 (6.6)
Male:female	7:9
Rural:urban	13:3
Duration of CSII therapy (months)	20.1 (14.6)

CSII=Continuous subcutaneous insulin infusion

Table 2: Differences pre- and post-CSII

Variable	Pre-CSII	Post-CSII	*P*
TDD insulin (units)	47.5 (25.4)	38.6 (13.5)	0.16
HbA1c (%), 3 months	11.4 (1.08)	8.0 (1.39)	0.001
No of hypos/month	3.06 (1.4)	1.4 (1.0)	0.001
No of hospitalisations	0.9 (1.8)	0.12 (0.3)	0.09

TDD=Total daily dose; CSII=Continuous subcutaneous insulin infusion

since CSII initiation on any of the 16 patients. Previous to this programme, 6 out of 17 had at least one admission with DKA. One of our dialysis patient had eight admissions with DKA when on the waiting list for a renal transplantation. Since initiation of CSII, he had no further admissions with DKA and went on to have a successful first combined kidney pancreas transplant in our region recently. The number of self-reported hypoglycaemic episodes reduced significantly post-CSII from a mean value of 3.0 episodes/month pre-CSII to 1.4 episodes/month post-CSII ($P = 0.001$). The number of severe hypoglycaemia needing hospitalisation reduced from a total of nine episodes in the preceding year in all patients pre-CSII to one admission a year post-CSII. The mean QoL score improved to 4.5 from a pre-CSII of 1.1. All the patients responded positively when asked whether they would suggest CSII therapy to anyone with type 1 diabetes.

The comments made by our patients ranged from a 'rebirth' to a 'perfect partner for life'. One of our type 1 diabetes mother from a poor socioeconomic status from a village had three miscarriages pre-pump and then went on to have a successful pregnancy and delivered recently on an insulin pump. Her quote was 'my insulin pump gave me the best gift of my life – my priceless baby'. Her HbA1c pre-pump was 10% and in spite of MDI during each of her previous pregnancies in a different centre, she had early trimester miscarriages. One of our patient in his senior high school year (Class 12) went to score the highest grade in his school and has joined an engineering course in a reputed institution. He commented that 'he can live his dream on the pump'. Overall, every patient commented that they did not feel like they had a disease, they felt free and the insulin pump had given them a new lease of life.

DISCUSSION

We have shown in our study that CSII in motivated rural Indian patients can make a real change to the lives of the underprivileged, with the help of the Institution–Industry–NGO partnership.

There are studies suggesting that providing access to insulin, blood glucose monitoring strips as well as access to medical care and education had a sustainable effect in 25 PWD following the introduction of MDI in indigent populations in India.[9] Such studies provide a rationale to use of inulin pumps in this population, from a technical and operational aspect. Thus patients failing MDI under such socioeconomic circumstances in the rural areas can obtain significant improvement in glucose control with insulin pumps, if given the right support.

Our patients, predominantly from the rural areas, showed a significant drop in HbA1c from 11.4 to 8% at 3 months ($P < 0.001$) that further reduced to 7.6% at 6 months and was maintained for a year. There was a numerical but non-significant reduction in TDD of insulin and no admissions with DKA for at least a year. The incidence of both self-reported hypoglycaemias and severe hypoglycaemias reduced significantly on CSII. There was a significant improvement in their QoL. Our results are consistent with a similar study done in an urban tertiary referral centre (Chennai, India) in 17 patients with type 1 diabetes.[10] In this study, the HbA1c in urban type 1 patients reduced from 10.6 to 8.8% at 6 months and 7.9% at 1 year. There were no admissions with DKA after CSII initiation in this urban study as well. Therefore, it is clear that the rural patients from lower socio-economic strata can do as well on the CSII therapy as urban affordable patients.

The question is whether we should go one step further in utilising technology like Carelink (internet-based insulin pump monitoring system) in our patients from the rural areas to optimise glycaemic control. Studies in the western world have shown that rural Carelink users had better glycaemic control and fewer hospital visits than non-users,[11] but the scenario in rural India presents unique challenges in installing such web-based software in terms of systems and training. At this point of time, all troubleshooting, dose adjustments and counselling are predominantly done through phone contacts, mobile texts and three monthly visits to the base hospital. Selected patients with challenging control have had ambulatory glucose profile to fine tune the basal and bolus rates. We propose to start using Carelink in selected rural patients to assess whether outcomes will be any different.

In summary, we have shown that CSII is a viable treatment option in type 1 diabetes patients from low socioeconomic strata in rural India. With studies showing that CSII not only improves QoL, but also reduces cardiovascular mortality compared to MDI,[12] we believe that it is unfair to withhold such therapy to deserving underprivileged patients from the rural areas. However, there are unique challenges in terms

of affordability, access, education and follow up. Improving access through governmental policies in association with industry and NGO's can utilise technology to benefit not only the rich but also to the poorer marginalised sections of the society.

Conflicts of interest

There are no conflicts of interest.

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