## Original Article:

# Comprehensive Management of Type 1 Diabetes in a Marginalized Population in Northern India: a Seven Year Retrospective Review

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### Abstract

Indian children with type 1 diabetes (T1D) from resource-poor families often have poor prognoses due to unavailability or unaffordability of care. We utilized a team-based approach to treat marginalized T1D children with multiple daily insulin injection (MDI) basal bolus regimen. In this study, a chart review of all 48 patients treated from 2006-2014 were included. A team-based approach comprising a physician, a diabetes educator and a community health worker were used. All patients were administered MDI of glargine and short-acting human insulin. Extensive diabetes self-management education tailored to culture, language, and literacy level was provided. Carbohydrate counting of local foods was introduced with patients utilizing home blood glucose monitoring. The structured program included home visits, telephone and internet support and group meetings. Age (Mean ± SD) at enrolment was 13.9  $\pm$  4.7 years (n=48), with 26 males (54%). For 25 patients followed for  $\geq$  3 years, HbA1c at baseline and years 1, 2 and 3 was (Mean  $\pm$  SD) 13.0  $\pm$  1.0%, (119  $\pm$  11 mmol/mol) 9.0  $\pm$  2.0%  $(75 \pm 22 \text{ mmol/mol}) 8.2 \pm 1.5\%$  (66 ± 17 mmol/mol) and 8.3 ± 1.4% (67 ± 15 mmol/mol), respectively and BMI improved from (Mean  $\pm$  SD) 15.4  $\pm$  2.4 to 19.0  $\pm$  2.9 kg/m<sup>2</sup>. The most recent median HbA1c for all patients was 8.6% (70 mmol/mol). There were no hospital readmissions with ketoacidosis or severe hypoalycemia, and one death from unknown causes. Integral to the program's success was provision of essential diabetes supplies and intensive locally-relevant diabetes education, including innovative approaches such as an internet-based support group. Our findings suggest that it is feasible to achieve successful and sustainable T1D management in an indigent population in rural India.

Key words: children, diabetes, developing countries, patient education, intensive therapy

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### Introduction

In 2013, IDF Diabetes Atlas estimated that there were approximately 497,100 children <15 years of age with type 1 diabetes (T1D) globally (1). The estimates for India were a prevalence of 67,700 (13.6% of global cases), with 10,900 new cases each year (1). This estimate is based on the T1D incidence study of Kalra et al., (2). There is some evidence of increasing T1D incidence and earlier onset (3). T1D care in India poses many problems as there is intermittent or no government supply of insulin, and no government support for supplying test strips, syringes and hemoglobin A1C (HbA1c) testing (4-8). Additional challenges include poverty, limited literacy, frequent unavailability of educational resources, cultural factors, and, due to the vast population, a limited coverage by doctors and nurses expert in this field (4,5,7-9). There is limited data on complication and mortality rates, but evidence suggests they are often high relative to well-resourced settings (6, 10).

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Good blood alucose control is critical for dangerous preventina hvpoand hyperalycemic extremes, and reducing chronic vascular and neuropathic diabetes complications. In the past, twice-daily injections of mixed insulin or of short- and intermediate acting insulin were used, and these regimens are still widely used in less-resourced settings (11). The basal-bolus concept, either as multiple dose insulin injection (MDI) or continuous subcutaneous insulin infusion (CSII), has led to improved glycemic control, or is now the recommended regimen, combined with selfmonitoring of blood glucose (SMBG), carbohydrate counting and diabetes education (12). The basal analog insulin glargine has a more predictable glycemic effect compared to NPH insulin with a reduced rate of hypoglycemia and greater treatment satisfaction (13-16).

In 2006, we undertook a daunting challenge to introduce the basal/bolus insulin regimen, along with intensive diabetes education, in an impoverished population of T1D patients in northern India. The project site is Rama Krishna Mission (RKM) hospital (17), a 150 bed multispecialty charitable hospital situated in the city of Haridwar, 150 km north of New Delhi. Haridwar has a population of 1.89 million people and also attracts a large number of pilgrims to holy sites. The hospital runs on donations and provides free- or low-cost care to the poor and minimally literate population in this region. Here the current study reported a seven-year follow-up on all 48 children and adolescents with TID enrolled in our program.

### Methods

### Subject enrolment

A chart review was performed on all 48 children and youth (age < 26 years) diagnosed with T1D from families with monthly incomes  $\leq$  10,000 INR (156 USD) treated at RKM hospital from September 2006 to April 2014. Signed informed consent was obtained from all subjects. A clinical diagnosis of T1D was made on all patients based on symptoms (history of polyuria, polydipsia, weight loss) confirmed by laboratory investigations, including blood  $\geq$ 11.1 mmol/L, ketones in urine, and elevated HbA1c level >6.5% (>48 mmol/mol).

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### Initial evaluation and insulin regimen

Initial evaluation was performed by a team consisting of a trained physician, a diabetes educator and a community health worker. All patients were initiated on MDI with glargine (Sanofi, France) and short-acting Humulin- (Eli Lilly, USA)) insulin, SMBG, dietary carbohydrate (CHO) counting, and diabetes selfmanagement education (DSME).

A 15-part questionnaire was used for initial evaluation of patients and their caregiver; to assess their literacy level, understanding of socioeconomic diabetes, status, family dynamics and psychological barriers. We implemented a five-day patient- and familycentered DSME program in hospital, comprising: one-on-one teaching to the family about T1D, rationale for basal/bolus concept of MDI for insulin replacement, and importance of SMBG and dietary CHO counting for insulin dose adjustments. Various methods, including stuffed toys, pictures and role-playing were used in a culturally sensitive manner, suited for the family's literacy level and learning style.

Initial total daily insulin dose (TDD) was calculated from the formula 0.5-1.0 U/kg/day, allowing for nutritional status and presence of acute insulin resistance factors (i.e. ketones, infection). 20-40% of TDD was given as basal glargine at bedtime. Short-acting insulin was used as a bolus dose, given 30 minutes before breakfast, lunch and dinner to cover CHO content and to correct elevated pre-meal blood glucose levels. Doses were calculated based on insulin: CHO ratio (ICR) and insulin sensitivity factors (ISF). ICR is the amount of CHO (in grams) covered by one unit of insulin; calculated as 500/TDD dose. ISF is the reduction in BG (mmol/L) expected by subcutaneous administration of one unit of insulin; calculated as 1500/TDD.

Daily adjustment of insulin doses, based on their pre-meal blood glucose and meal CHO count was performed by the patient and their caregiver with guidance by the diabetes care team while in the hospital, and continued at home for at least two weeks by phone until the patient and the caregiver were confident with insulin dose adjustments. All patients were provided free insulin, insulin syringes, and glucose monitoring supplies (International

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Diabetes Federation Life for a Child Program, Insulin for Life USA, Australia and Manav Seva Foundation Inc., USA).

#### Designing an appropriate diet

Since the majority of the patients were initially in a catabolic state, sufficient calories were assigned until they had regained an acceptable weight. The concept of а balanced diet with various classes of food was explained using a plate method as well as pictures and food models. A list of CHO counts on Indian food was developed through various sources (18-20). The list included cooked food in 15 gm CHO values by weight for solid foods and by volume for liquid foods in all categories. Patients were asked to bring a sample of their daily diet to the hospital. typical А carbohydrate value was assigned to each component of cooked food per serving based on the weight and volume of their meal. The same procedure was followed for dairy, fruits and snacks.

Patients were taught how to read prepackaged food labels for CHO content per serving. Using a three-colored basket method (red, yellow, and areen, as with traffic lights) children were encouraged to use food / snacks from the green rather than the red basket and sometimes use food from the yellow basket. The choice gave some freedom and aided dietary adherence. The training enabled them to visually recognize 15 g CHO in a variety of foods, giving them control and confidence to calculate their insulin doses when away from home. Various games, art-work and quizzes were used to reinforce CHO counting, which appealed to the children, who readily adopted the counting.

### Glucose monitoring

All patients were given a blood glucose meter (BGM) to check their blood sugar three times at pre-meal, with an additional test performed when hypoglycemic symptoms occurred. A logbook was maintained by the families and verified against their BGM during clinic visits. Families and children were educated to make a connection between their blood glucose levels and symptoms of hypoglycemia, as well as the effect of food and exercise on their glucose levels. Children  $\geq$  eight years were

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required to check their own blood glucose and administer their own injections at home and in school. Children and their families were required to carry a "hypo pack" containing 15 g of raisins and nuts at all times to treat hypoglycemia (21). HbA1c was measured every four months with a point-of-care (initially with A1cNow+ kits (Bayer HealthCare, USA) and from January 2013 with DCA Vantage machine (Siemens Healthcare, USA)), to allow face-toface discussion and immediate changes in their treatment. If HbA1c was >13% (>119 mmol/mol) a value of 13.5% (124 mmol/mol) was used in data analysis.

#### Support and follow-up

A community health worker visited new patients in their homes, reinforcing CHO counting, checking their BGM and logbook, provided supplemental and diabetes education as needed. Each family was provided with a copy of a diabetes manual: "Living the sweet life: Diabetes and the art of balancing insulin with diet and exercise" (copies available on request). This guide, written at a 6<sup>th</sup> grade reading level and translated into Hindi, also includes a list of CHO values of common Indian foods. Children and their families were required to attend a health professional-moderated international internetbased support group "Penpals United" (22) (established for this purpose) on a monthly basis, which allowed children to meet with TID, American peers and were encouraged to be open about their condition and express their feelings, through a translator. The internet based program called Penpals United is run by four young adults with T1D in USA. Often a celebrity guest with T1D is invited. Parents also found support from each other, sharing their challenges of caring for a child with T1D.

### Statistics

Data were managed in Excel. Descriptive statistics were performed in Excel and change in HbA1c and BMI over time was assessed by paired two-tailed t-tests. Statistical significance was taken at p<0.05.

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Year of follow-up	Baseline	1	2	3	4	5	6	7
n	48	40	32	25	13	8	5	3
Age (years)	13.5 (4.6)	14.6 (4.9)	15.5 (4.6)	15.5 (4.3)	16.0 (3.8)	15.6 (3.1)	17.6 (1.7)	18.3 (1.0)
Male, Female	26, 22	22, 18	18, 14	14, 11	7,6	5, 3	3, 2	2, 1
TID duration (years)	2.0 (3.5)	3.0 (3.6)	4.3 (4.0)	4.6 (3.2)	5.6 (3.8)	5.1 (0.7)	6.1 (0.8)	7.6 (0.3)
Insulin dose U/kg/day	1.30 (0.52)	1.02 (0.33)	1.02 (0.33)	0.94 (0.33)	1.1 (0.24)	1.03 (0.24)	0.90 (0.02)	1.06 (0.11)

Table 1: Clinical characteristics at baseline (initial visit to the clinic) and follow-up for all 48 patients out to seven years of follow-up.

Results are (mean (SD), TID: type 1 diabetes



Figure 1: Change in mean HbA1c for all 25 patients followed for at least three years

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Figure 2: Mean HbA1c and BMI for each year of follow-up out to seven years for all 48 patients

#### Results

Forty-eight children with T1D 26 (54%) male, 22 (46%) female), were included in the chart review at the end of April 2014. Most (n=46) were cared for in Haridwar and two in Vrindaban. Nearly all (n=47) families had a monthly income  $\leq$ 5,000 INR ( $\leq$ 84 USD) with one family having an income of 10,000 INR (156 USD). Highest formal education of either parent was  $\geq$ 6<sup>th</sup> grade in 17 families, <6<sup>th</sup> grade in 20 and nil in 11. The mean  $\pm$  SD age at diagnosis was 11.8  $\pm$  4.8years (range 3.4 to 21.3 years), and mean age at enrolment was 13.9  $\pm$  4.7 years. Duration of

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diabetes from diagnosis to end of study was 4.9  $\pm$  3.8 years, with duration in the program  $2.8\pm2.0$  years.

Twelve patients in the program had new onset T1D, were treated with MDI with in four weeks. 36 children had previously been treated before enrolling into the program with two injections of premixed insulin (70/30) for an average of 2.7±3.2 years, out of which three were treated at RKM Haridwar. One of these had been prescribed insulin but this was rejected by the family in favor of traditional medicine, in spite of continued deterioration to a cachectic state.

For the whole group of 48, baseline BMI was 15.4 $\pm$ 2.4 kg/m<sup>2</sup> and insulin dosage was 1.3 $\pm$ 0.5 U/kg/day. Enrolment of HbA1c for the 36 subjects in the pretreated group was 12.7  $\pm$  1.5% (115 $\pm$ 16 mmol/mol) with no subject under 7.5% (58 mmol/mol) 2 (5%) 7.5-8.9% (58-74 mmol/mol), 11 (30%) 9-12.9% (75-117 mmol/mol) and 23 (65%)  $\geq$ 13%. ( $\pm$ 119 mmol/mol) Many were very underweight - mean BMI was 15.2  $\pm$  2.5 kg/m<sup>2</sup>, with 12 boys (57%) and 5 girls (31%) < 3rd centile (23). Further information on clinical characteristics is presented in Table 1.

Many patients took insulin irregularly and were dependent on a neighborhood health care provider for their injections. Blood glucose monitoring had consisted of a fasting and postprandial blood sugar that was performed once every 2-3 months, with no other laboratory monitoring. No patients had previously received formal diabetes education or dietary instructions. None were on SMBG. At the time of their first visit to clinic, seven patients had bilateral cataracts (mean duration of disease 4.5 years (range 2-7)). Three patients had peripheral neuropathy, and had a history of foot ulcers, and one patient had already had amputations of two toes. Two patients had the classic triad of Mauriac Syndrome (24).

For the 12 children who presented to the clinic with new onset T1D from 2009, age at baseline was  $11.2 \pm 5.0$  y, BMI  $15.7 \pm 2.2$  kg/m<sup>2</sup> and HbA1c  $13.2 \pm 1.0\%$  (121 ± 11 mmol/mol) All received insulin within four weeks of initial symptoms.

### Education and support group sessions

In 2011, each family (n=24) attended an average of  $6.4 \pm 2.9$  face-to-face diabetes education sessions, each lasting 1-2 hours. This increased to 17.8  $\pm$  8.6 sessions in 2012 (n=34), and 24.0  $\pm$  11.3 sessions in 2013 (n=45), which included education by mobile phone. Attendance of each family at support group sessions of three hours (combined local- and internet-based), averaged 6.3  $\pm$  1.7 in 2011 (n=4), 6.8  $\pm$  3.0 (n=36) in 2012, and 7.4  $\pm$  2.5 in 2013 (n=46).

### **Clinical progress**

For 25 patients followed for  $\geq$ 3 years, HbA1c at baseline and years 1, 2 and 3 was (mean ± SD) 13.0 ± 1.0% (119 ± 11 mmol/mol) 9.0 ± 2.0% (75 ±

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22 mmol/mol) 8.2  $\pm$  1.5% (66  $\pm$  16.5mmol/mol) and 8.3  $\pm$  1.4% (67  $\pm$  15mmol/mol) respectively (see Figure 1), and BMI improved from (mean  $\pm$ SD) 15.4  $\pm$  2.4 to 19.0  $\pm$  2.9 kg/m<sup>2</sup>. Figure 2 shows the pattern of change of HbA1c and BMI for all patients.

One child, lost to T1D follow-up died of unknown causes towards the end of the study period. Mortality rate during the study period was 4.3 per 1,000 years of diabetes. There were no readmissions to the hospital with ketoacidosis or severe hypoglycemia since program inception. One child was admitted with a viral illness and another for drainage of an abscess unrelated to injection sites.

### Status at end of follow-up

Age of the subjects were  $16.7 \pm 4.6$  years (n=47). 8 subjects (17%) had a HbA1c  $\leq 7.5\%$  ( $\leq 58$  mmol/mol) 22 (47%) were 7.6 < 9% (60 < 75 mmol/mol), 13 (28%) 9 - 12.9% (75-117 mmol/mol) 4 (8%) were  $\geq 13\%$ . ( $\geq 119$  mmol/mol) Mean HbA1c at the end of the study was 9.2  $\pm$  2.0% (77  $\pm$  22 mmol/mol) median 8.6% (70 mmol/mol).

Out of the seven children with cataract, four have undergone surgery and their vision restored and three are at various stages of their treatment. One patient had diabetic retinopathy and another severe corneal scarring. The two patients with Mauriac Syndrome made a complete recovery.

Out of the 47 surviving subjects, 31 are attending school, 12 have completed school and are working, three girls are married and raising a family and one girl is home-schooling.

### Discussion

To the best of our knowledge, this is the first publication to describe use of MDI to treat T1D in a wholly indigent population in India.

The Indian Society of Pediatrics and Adolescent Endocrinology's Clinical Practice Guidelines (25) and the Consensus Statement of Diabetes in Children (8) recognize the basal/bolus regimen as a preferred method of T1D treatment. However, introduction of this regimen is challenging due to the cost of frequent blood glucose monitoring, the very limited teaching of DSME and carbohydrate counting, illiteracy in some families, cultural

barriers to diagnosis and treatment, and limited access to medical care in rural regions. As a result, there is likely a high incidence of early deaths and serious complications in many who survive; although published data is limited (6,10). A number of the previously-diagnosed subjects in our study had malnutrition, and diabetes complications such as cataracts and amputations. The high prevalence of cataracts is of concern. Acute cataracts can occur in newly diagnosed T1D cases (26), with permanent cataracts associated with increasing age and with other complications (27).

This study demonstrates that successful use of MDI in indigent populations in India is feasible, as evidenced by the fact that most program participants were able to maintain average HbA1c levels comparable to some developed country clinics (28). There was only one death in the study period (where previously at this hospital there had been no long-term survivors of childhood T1D). Furthermore, there have been no readmissions to the hospital with DKA or severe hypoglycemia since the inception of this program. Another positive outcome is that three women have married and had healthy children. This would have been unthinkable in this part of rural India prior this program. Saini et al., (16) has also achieved good results with MDI and glargine in a six-month study in a tertiary care center in Northern India.

There are a few important limitations to this study. The number of subjects was small since only 25 have greater than 3 years of follow up, though this is likely longer than their life expectancy without our program. Moreover, a presumptive diagnosis of T1D was made based on clinical features alone as autoantibody and C-peptide assays could not be performed. Therefore it is quite possible that some may have type 2 diabetes (T2D) or an atypical form of diabetes (6), but none clearly exhibited T2D.

The key of our program's success was the use of DSME, presented in a culturally sensitive and relevant manner. In order to achieve this, several innovative solutions were developed:

1) Screening questionnaires in the local language

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2) Customized, family-centered, culturally sensitive DSME program matched the literacy level of the patients;

3) New resources to teach patients how to perform CHO counting with local foods

4) Monitoring of adherence through sensitive and non-threatening means such as quizzes and games

5) Participation in an international support group to provide positive role models and encouragement. Professionally led support groups have been shown to be effective by Markowitz and Laffel (29). To our knowledge our internet support group Penpals United is the first such international group.

We have also established a Certified Diabetes Educator, India (CDEI) program located at a nursing school of RKM Hospital at Vrindaban, and now recognized by the IDF (30). Moving forward, training programs for diabetes educators will be essential to achieve widespread success in India.

### Conclusion:

Here we present a model for other centers to introduce a MDI approach to achieve successful and sustainable T1D management in India. Integral to the program's success was intensive locally-relevant diabetes education, availability of diabetes supplies, and the use of innovative approaches including an internetbased support group.

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