### **Original Article**

# Insulin Usage and Practices in Children and Adolescents with Type 1 Diabetes

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### Abstract

**Context:** Data on insulin usage and practices in children and adolescents with type 1 diabetes (T1D) is sparse in India. **Aims:** To analyze the various insulin types and regimens used by children and adolescents with T1D, the techniques and the devices used for insulin administration, and the storage and disposal methods of delivery devices. **Settings and Design:** Observational cross-sectional study. **Methods and Materials:** Study subjects were children and adolescents with T1D  $\geq$ 6 months and informed consent was obtained. A detailed demographic history was collected, and a predesigned, pretested questionnaire was used. **Results:** The number of subjects were 90 (M: F; 32:58), age ranging from 3 to 18 years and duration of T1D was 6 months to 16 years. Mean age was  $13 \pm 4.6$  yrs, HbA1c was  $9.11 \pm 2.2\%$  and duration was 5 years. Conventional insulins were more commonly used than analogs. Basal-bolus (BB) regimen was used in 49% of the subjects. Mean HbA1c for analogs was 7.6% and conventional was 9.3% (p = 0.001). HbA1c <8% was significantly more in those aged 3-8 yrs, mean duration  $\leq$ 4.1 yrs, those using pens and BB regimen. Fifty-six percent were using own refrigerators for storage and the most common barriers for insulin usage were fear of hypoglycemia (37%), inaccessibility (20%), and apprehension of shots (18%). Site rotation patterns were followed by 84% and 94% of the subjects reported disposing syringes and sharps as general waste. **Conclusions:** Conventional insulins and vial-syringes remain the most commonly used insulin delivery systems. Glycemic control was better in younger age, lesser duration, BB regimen, analog usage, and pen devices.

Keywords: Adolescents, children, insulin, type 1 diabetes

#### INTRODUCTION

Insulin remains the main stay of treatment in Type 1 Diabetes (T1D). Affordability, acceptability, accessibility, and administration are the major issues faced with insulin usage. Affordability of insulin is the main obstacle in children and adolescents belonging to lower socioeconomic strata in India. They obtain insulin either by purchasing or procuring it from the government hospitals. There are problems with government supply like shortage and lack of supply of all insulins. With improved diabetes education regarding complications and avoidance of hypoglycemia, acceptability of insulin has improved. Accessibility to insulin remains a hindrance when there is shortage and lack of facilities at home, school, and workplace. Correct administration of insulin involves using the right insulin, dose, regimen, and technique. Storage of insulin remains a problem for people who do not own refrigerators. The present study aims to look at the insulin types, regimens, techniques, storage, and disposal associated with insulin usage.

# Access this article online Quick Response Code: Website: www.ijem.in DOI: 10.4103/ijem.IJEM\_92\_21

The objectives of the present study are to analyze the various insulin types and regimens used by children and adolescents with T1D, the techniques of insulin administration, the devices used and the storage and disposal methods of delivery devices.

# **SUBJECTS AND METHODS**

This in an observational cross sectional study

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Submitted: 25-Feb-2021	Revised: 28-Feb-2021		
Accepted: 29-Mar-2021	Published: 21-Jul-2021		

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How to cite this article: Donepudi A, Donepudi HS, Ayyagari M. Insulin usage and practices in children and adolescents with type 1 diabetes. Indian J Endocr Metab 2021;25:38-42.

#### Study subjects

Subjects enrolled are children and adolescents with T1D between the ages of 3-18 years with duration of T1D and insulin usage for at least 6 months. The subjects were obtained from the diabetic child society (DCS) camps conducted once in 3 months at Visakhapatnam. DCS, established in 2014 organizes half-day diabetes camps for children and their parents. Point of care A1c, retinal check, supply of glucometers, strips, and insulin along with diabetes education are the main activities at the camps.

#### Study tool

A predesigned and pretested questionnaire was prepared based on the objectives of the study. Pretesting was carried out in a pilot study with 10 patients to check for clarity of the questionnaire. Necessary changes were then made. The insulin types used by the subjects were categorized as conventional and analogs for both basal and bolus insulins. A1c was done in all the subjects.

## **Data collection**

A detailed demographic history was collected in all the subjects. Socioeconomic status was assessed using the updated Kuppuswamy's socioeconomic scale.<sup>[1]</sup> Written consent was taken from all the subjects who were able to understand and in those young children that did not understand ascent was obtained from their parents. Questions were asked based on the predesigned questionnaire in their local language.

#### **Statistical analysis**

Quantitative data was presented as mean  $\pm$  SD. Categorical data was presented as percentages. The test of significance used were Chi square test, t test and Anova test. *P* value < 0.05 was considered statistically significant.

The questionnaire included demographic data, disease details, insulin type, regimen, devices, storage and problems faced in administration. The method of disposal of sharps was obtained.

# RESULTS

The total number of subjects were 90 (M: F; 32:58) and their baseline characteristics are shown in Table 1. Age of the subjects ranged from 3 to 18 years and duration of diabetes from 6 months to 16 years. Age of onset of diabetes was divided into 3 categories in which 55% of subjects were between 3 months and 8 years, 24% between 9 and 12 years, and 21% between 13 and 18 years. 69% of the subjects had duration between 6 months to 5 years, 22% between 5 to 10 years, and 9% more than 10 years. The characteristics of the subjects according to age distribution is shown in Table 2. The insulin regimens used by the subjects were basal bolus (48.9%), thrice daily (24.4%), split mixed (14.4%), and premixed (12.2%). The mean A1c in BB regimen was  $8.6 \pm 2.3$  and it was  $10 \pm 1.8$  for other regimens. Table 3 shows the different parameters influencing glycemic control. Delivery devices used by the subjects were syringes (62%), pens (29%), and pens + syringes (9%). Mean A1c of different delivery devices is shown in Figure 1. Site rotation patterns were followed by 84% of the subjects whereas 16% did not. Figure 2 shows the barriers faced with insulin usage. Figure 3 shows the methods of insulin storage. Totally, 94% of the subjects reported disposing syringes and sharps as general waste into the trash can and 6% reported collecting the sharps and disposing separately/bringing them to the hospital for proper disposal.

### DISCUSSION

The present study showed that conventional insulins are being used by 80-85% of children with T1D. However, it was noted that children in the age group 3-8 had higher usage of analog insulins, probably because of the lower dose and hence less cost. According to Hartman et al., rapid-acting insulin analogs have the advantage of mimicking the physiological mealtime insulin response more closely than regular insulin and can lead to a better glycemic response.<sup>[2]</sup> In the present study there was a significantly lower mean A1c in subjects who used analogs (7.6%) as compared to conventional insulins (9.3%). A similar study done by George Grunberger explained that analog insulins have improved treatment adherence and satisfaction due to fewer injections, flexibility, and user friendly injection devices.[3] Therefore, the present study reemphasizes the need for analog usage and user friendly injection devices for better glycemic control in children with T1D. However, analog usage needs support from government and non government organizations in children with T1D.

BB regimen is the most common regimen used at 49% in this study compared to 10% in an earlier study conducted in a similar cohort.<sup>[4]</sup> This could be attributed to increased awareness due to repeated diabetes education, leading to better acceptance. The premixed insulin is chosen mostly because of patient and doctor convenience and the advantage of twice-daily dosing; however, it does not offer the dosing flexibility of BB regimens and is associated with more hypoglycemic episodes. BB, though ideal for better glycemic control, is usually less acceptable because of the number of insulin shots.<sup>[5]</sup> In the present study, subjects using BB regimen had a lower mean A1c ( $8.6 \pm 2.3$ ) compared to subjects using

Table 1: Baseline characteristics of the subjects				
Parameter	Value	Р		
Mean age (yr)	13±4.6	-		
Mean HbA1c (%)	9.11±2.2	-		
Mean duration (yr)	5.13±3.95	-		
Conventional insulin, n (%)				
1. bolus	78 (87%)			
2. basal	72 (80%)			
Analog insulin, n (%)		0.008*		
1. bolus	12 (13%)			
2. basal	18 (20%)			
Mean HbA1c for conventional insulin	9.3%			
Mean HbA1c for analog insulin	7.6%	0.001*		
*Conventional vs Analog				

\*Conventional vs Analog

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Table 2: Characteristics distributed by age						
3-8	9-12	13-18	Р			
18.89	26.67	54.44	-			
8.32±1.86	8.74±2.34	9.57±2.17	0.041			
10 (59%)	8 (33%)	12 (24%)	-			
$0.98{\pm}0.36$	$0.9230 \pm 0.39$	0.950±0.32	-			
13 (76.48%)	22 (91.66%)	43 (87.75%)	-			
12 (70.58%)	20 (83.33%)	40 (81.63%)				
4 (23.52%)	2 (8.34%)	6 (12.25%)	-			
5 (29.42%)	4 (16.67%)	9 (18.37%)				
6.9%	7.3%	8.5%	0.043*			
9.2%	8.9%	9.8%				
	<b>3-8</b> 18.89 8.32±1.86 10 (59%) 0.98±0.36 13 (76.48%) 12 (70.58%) 4 (23.52%) 5 (29.42%) 6.9%	3-8         9-12           18.89         26.67           8.32±1.86         8.74±2.34           10 (59%)         8 (33%)           0.98±0.36         0.9230±0.39           13 (76.48%)         22 (91.66%)           12 (70.58%)         20 (83.33%)           4 (23.52%)         2 (8.34%)           5 (29.42%)         4 (16.67%)           6.9%         7.3%	$3-8$ $9-12$ $13-18$ 18.8926.6754.44 $8.32\pm 1.86$ $8.74\pm 2.34$ $9.57\pm 2.17$ 10 (59%) $8 (33\%)$ 12 (24%) $0.98\pm 0.36$ $0.9230\pm 0.39$ $0.950\pm 0.32$ 13 (76.48%)22 (91.66%)43 (87.75%)12 (70.58%)20 (83.33%)40 (81.63%)4 (23.52%)2 (8.34%)6 (12.25%)5 (29.42%)4 (16.67%)9 (18.37%)6.9%7.3%8.5%			

\*Analog vs. Conventional

Table 3: Parameters Affecting Glycemic Control					
	HbA1c <8%	HbA1c >8%	Р		
Duration of diabetes (mean)	4.1±3.6	7.3±3.5	0.002		
Pen, <i>n</i> (%)	19 (69%)	8 (31%)	0.027*		
Syringes, n (%)	11 (20%)	45 (80%)			
Analogs, n (%)	9 (61%)	6 (39%)	0.044**		
Conventional, n (%)	23 (30%)	52 (70%)			
Basal bolus, <i>n</i> (%)	20 (45%)	24 (55%)	NS		
Other regimen, n (%)	13 (28%)	33 (72%)			

\*Pens vs Syringes. \*\*Analog vs Conventional

other regimens  $(10 \pm 1.8)$ . This was not statistically significant, though there was a trend, which could be due to the small sample size.

The present study showed a lower mean A1c (9.11%) compared to a previous study done in a similar population (10.17%).<sup>[4]</sup> The best average A1c was seen in the age group 3-8 years (8.32%). This could be due to parental care, analog usage, better compliance with medication, diet, and physical activity. In this study, poor glycemic control was 41% in those aged 3-8, 67% in those aged 9-12, and 76% in those aged 13-18 years which was statistically significant. This shows that as age increases glycemic control deteriorates, similar to a study done by Hanna. A Mohammad et al. in Egypt. In their study, it was seen that in children aged 15 years and more, 67.9% had poor glycemic control compared to 25.6% in children aged less than 10 years.<sup>[6]</sup> In the present study it is seen that longer duration of diabetes is associated with significantly poor glycemic control. The subjects with A1c <8 had a mean duration of diabetes of  $4.1 \pm 3.6$  years whereas those with A1c >8 had a mean duration of  $7.3 \pm 3.5$  years. Similarly, Hanna et al. in Egypt reported that patients with poor glycemic control had significantly longer duration of disease than patients with good glycemic control  $(4.94 \pm 2.6 \text{ vs } 3.40 \pm 2.0)$ .<sup>[6]</sup>

The subjects using syringes for insulin delivery were 62%, pens were 29% and both pens and syringes were 9% in this study. In a study conducted by Manash P. Baruah *et al.* in adults with type 2 diabetes in India, pen devices were used by

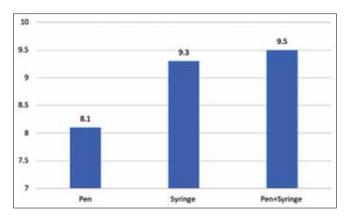
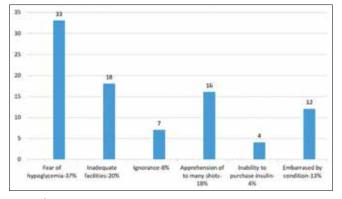


Figure 1: Mean HbA1c (%) for pen, syringe, and pen+syringe

66.08%, whereas 31.76% used syringes, and 2.15% were using both pens and syringes.<sup>[7]</sup> This difference could be because of varying demographics and socioeconomic status. Majority of children with T1D were using 6-mm needle syringes and 4-mm needle pens. However, 8-mm needle syringes which were supplied by the government hospital are also used by the subjects. Usage of 8-mm needles is associated with intramuscular delivery, especially in children and also at 90° angle. According to FIT India guidelines, shorter needles should be preferred over longer needles.<sup>[8]</sup> Improper technique of injecting insulin causes mismatch of peak insulin effect and maximal glucose load leading to poor glycemic control. In a previous study, it was shown that site rotation patterns were followed in 75% of patients, while it improved to 85% in the present study.<sup>[4]</sup> According to the FIT guidelines, systematic site rotation is important as it helps maintain healthy injection sites, optimizes absorption of insulin and reduces the risk of lipohypertrophy.<sup>[8]</sup> These techniques help maintain proper glycemic control. As explained by Down S et al., an effective way to implement site rotation is to divide the injection site into quadrants (abdomen) or halves (thighs, buttocks, and arms). One quadrant or half should be used for 1 week and then move either in a clockwise or an anticlockwise manner to another quadrant or half next week.<sup>[9]</sup>

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**Figure 2:** Barriers faced with insulin usage

For optimal effect, insulin needs to be stored under refrigerated conditions, between 2 and 8°C, and be protected from light when vials or pens are unopened. Pens or vials in use may be kept at room temperature, protected from sunlight, up to 25°C. Exposure to higher temperatures during storage and use may degrade insulin by hydrolysis, or transform it to higher molecular weight components.[10] A study performed in Puducherry, India, showed that storage of regular and biphasic insulin at 32°C to 37°C decreased the potency of insulin by 14 to 18%.<sup>[11]</sup> In our study, 56% of the subjects used their own refrigerators, 20% used neighbors refrigerators, while 13% used clay pots and 11% used ice packs. Clay pots and ice packs are not optimal for insulin storage and may lead to decreased efficacy of insulin. In India, insulin storage is a major challenge in view of the tropical weather, power shortage, and lack of proper storage facilities at home as evident in this study. Kalra et al. from Haryana has highlighted these problems in his earlier study.<sup>[10]</sup> A study done by G.D Ogle et al., compared 13 traditional cooling devices used for insulin storage based on temperature reducing efficacy in families that did not have access to home refrigeration. The study highlighted that storage in clay pots reduces the temperature of storage by 8.7°C compared to storage in an open shady area.<sup>[12]</sup> The barriers for insulin usage were most commonly fear of hypoglycemia (37%) followed by inadequate facilities at school (20%), apprehension of too many shots (18%), embarrassment (13%), and ignorance (8%) about the condition and inability to procure enough insulin (4%). There is lack of awareness on proper disposal of delivery devices, syringes, and needles. In the present study, 94% of subjects were disposing along with household trash. Only 6% were disposing the sharp waste separately or bringing it to the hospital. There is a need to educate the subjects regarding sharp disposal and the dangers associated with improper disposal.

The limitations of the present study are small sample size, selection bias due to majority belonging to lower/lower middle/ middle socioeconomic strata. The data were obtained using close ended questions and was dependent on the subject's answers. Selection of children and adolescents with T1D is the main strength of the study because there is sparse data in

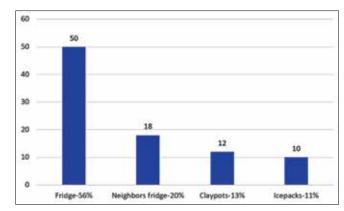


Figure 3: Methods for storage of insulin

this field. The study showcases the problems of insulin usage faced by the children and adolescents with T1D and looks to supply a solution to them.

# CONCLUSION

The study highlights the present-day insulin practices of young T1Ds. Conventional insulins and vial-syringes remain the most commonly used insulin delivery systems. Glycemic control was better in younger age, lesser duration, BB regimen, analog usage, and pen devices. The reasons for not using BB regimen, pens, and analogs are due to nonaffordability, lack of awareness and financial constraints. Therefore, the study re-emphasises the need to work for improved support in children with T1D. Diabetes education of T1Ds and their parents for appropriate therapy and proper disposal of sharp waste is the need of the hour.

# Financial support and sponsorship Nil.

#### **Conflicts of interest**

There are no conflicts of interest.

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