3. METHODOLOGY

The methodology of the study is presented under the following headings:

3.1: Research Design
3.2: Selection of Hospitals
3.3: Statutory Clearance
3.4: Selection of Subjects
3.5: Research tool- Interview schedule
3.6: Assessment of Nutritional status
   3.6.1: Dietary Assessment
      3.6.1.1: 24 hours dietary recall method
      3.6.1.2: Food frequency questionnaire
      3.6.1.3: Carbohydrate counting
   3.6.2: Anthropometric measurements and indices
      3.6.2.1: Height, Weight
      3.6.2.2: Height and Weight Percentiles
      3.6.2.3: BMI Percentiles
3.7: Clinical parameters and Biochemical estimations
   3.7.1: Blood Pressure Levels
   3.7.2: Blood Glucose Levels
   3.7.3: Glycosylated Haemoglobin levels (HbA1c)
3.8: Calculation of Insulin dosage
   3.8.1: Calculation of total insulin dosage based on body weight
   3.8.2: Calculation of bolus insulin dosage as per CHO intake
3.9: Quality of Life
3.10: Nutrition Education- Intervention
   3.10.1: Individual counselling
   3.10.2: Group counselling
3.11: Statistical analysis of data
### 3.1: RESEARCH DESIGN

#### INSTITUTIONS

- **SAGAR HOSPITALS (SH)**
  - *(n= 50)*

- **INDIRA GANDHI INSTITUTE OF CHILD HEALTH (IGICH)**
  - *(n= 82)*

#### Subjects
- *(n= 132)*
  - **Males** *(n= 60)*
  - **Females** *(n= 72)*

#### Data

#### STATISTICAL ANALYSIS AND INTERPRETATION OF DATA

#### Intervention Program

#### Reassessment

- **Dietary pattern**
- **Anthropometric measurements**
- **Blood glucose, HbA1c, Insulin intake**
- **Quality of Life**
- **Life-style pattern**
- **Insulin dosage**
3.2. SELECTION OF HOSPITALS

Indira Gandhi Institute of Child Health (IGICH) a government hospital and Sagar Hospitals, Jayanagar (S.H) a corporate hospital were selected for the study.
Indira Gandhi Institute of Child Health is a premier organization promoting tertiary level child health care services functioning under the control of Ministry of Medical Education, Government of Karnataka. It is non-profit organization aided by Government of Karnataka, located in south Bangalore. It is a government hospital with multispeciality and super-specialty 250 bedded hospital for children and a postgraduate institute of higher medical sciences with the state of the art facilities such as dietitian service, paediatric intensive care, neonatal intensive care, paediatric surgery with well equipped ventilators support, well equipped laboratory and radiodiagnosis departments etc. Hospital has many specialties Paediatric Ortho, Paediatric Nephrology, Neurology, Child Guidance, Paediatric Endocrinology, Pulmonology, ENT, Genetics, Paediatric Plastic Surgery and Paediatric Cardiology. Available drugs are provided free of cost to the OPD patients.

The Sagar Hospitals a corporate tertiary care multi-specialty hospital, Jayanagar, Bangalore with 250 beds is a landmark healthcare services institution that enjoys a unique reputation of being a popular destination for both Indian and international patients seeking treatment at an affordable cost. The Sagar Hospitals mission is to maintain a high degree of quality and care to any patient seeking medical aid is sacrosanct to its highly acclaimed and equipped team with the state-of-the-art medical equipments. It’s well planned nursing with a high degree of attention to hygiene and ambiance help the recuperating patients be in a pleasant environment. It is NABH, NABL accredited and ISO 9001 certified with 24 hour pharmacy, laboratory, blood bank, high tech ambulance and blood bank, centre for diabetes and endocrinology, well established dietary department, day and night cafeteria with 24 hour food service along with special services like Preventive/Executive Health Check Dept, Home Health Care, Daycare Centre etc.

3.3: STATUTORY CLEARANCE

Approval and ethical clearance was obtained from the hospitals to conduct the study. The subjects and parents were also informed and explained about the study and the written consent was obtained individually from both the children and parents in case of above 10 years age and only parents in case of the subjects below 10 years of age.
3.4. SELECTION OF SUBJECTS

The subjects (n=132) belonging to the age group of 1–18 years were selected from out-patient diabetic clinics of the two hospitals by purposive sampling. Out of the subjects selected, 50 were from S.H and 82 were from IGICH. Out of the total subjects selected 60 were male and 72 were female subjects.

**Inclusion criteria:** The subjects who are diagnosed as diabetic either type 1 or type 2 in the age group of 1-18 years were included in the study.

**Exclusion criteria:** Diabetic children with mental disability, suffering from terminal illness and who are on insulin infusion pumps were excluded from the study.

3.5: RESEARCH TOOL - INTERVIEW SCHEDULE

An interview schedule was developed with the consultations of an endocrinologist, biochemist and statistician to collect the relevant information related to the research topic. The schedule developed was pretested on 10 per cent of the sample and modified suitably. The modified interview schedule was administered personally both on the children and their parent who accompanied the child on a regular basis and in majority of the cases it was the mother of a child. Clinical data was collected from the medical records and biochemical estimations were done according to the standard procedures. Pediatric Symptom Check list - Euro QOL questionnaire was used to check the quality of life.

3.6: ASSESSMENT OF NUTRITIONAL STATUS

3.6.1: Dietary Assessment

**3.6.1.1: 24 hour dietary recall method:** A 24-hour dietary recall method was used to collect the information pertaining to dietary intake. A set of cups with varying capacities (volumes) were standardized and numbered and used to collect the
information. Standardization of measuring vessels / cups and converting cooked food to raw ingredients was done as per the procedure of Thimmayamma and Parvathi Rao (1996). Nutritive value of the raw equivalents was calculated using the food composition table (Gopalan et al., 2009) and the nutrient adequacy was calculated using the following formula.

\[
\text{Nutrient adequacy} = \frac{\text{Nutrient intake}}{\text{RDA of the nutrient for particular age and sex}} \times 100
\]

The mean calorie contribution from carbohydrate, protein and fat was calculated and compared with the recommended values for diabetic children as per Smart et al., (2009).

Carbohydrates = 50-55% total Calories
Proteins = 10-20% total Calories
Fat = < 30% total Calories

3.6.1.2: **Food Frequency Questionnaire:** Food Frequency Questionnaire (FFQ) is the standard method to collect dietary data in studies of chronic disease all over the world. This is most commonly used method to assess the diet and its relation to chronic disease. First step of this method is to identify and organize the list of most commonly consumed foods of the study population and to assess the frequency of intake of foods varying from “never or less than once a month to daily”. This method is inexpensive, more representative and easy to implement (Damayanthi and Radhika, 2010).

3.6.1.3: **Carbohydrate Counting:** Foods that contain carbohydrate will raise the blood glucose hence, by keeping track of the amount of carbohydrates ingested and calculating the bolus insulin dosage will help to keep blood glucose levels in target range. Carbohydrate Counting or Carb Counting (1CHO Count=15 gms of CHO) is a feasible meal planning technique which helps the patients or their care-takers to find out the carbohydrate ingested by the children. The carbohydrate content of every meal of the child was calculated and compared with the standards given by Gail Spiegel and Monica Penkilo (2010).
Carbohydrate amounts by Age

<table>
<thead>
<tr>
<th>Boys</th>
<th>&lt; 5 years old</th>
<th>5–12 years old</th>
<th>Teens</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30 to 45 gms / meal</td>
<td>45 to 60 gms / meal</td>
<td>60 to 75 gms / meal</td>
</tr>
</tbody>
</table>

| Girls           | 30 to 45 gms / meal | 45 to 60 gms / meal | 45 to 75 gms / meal |

Snacks are usually 15 to 30 gms of carb.

3.6.2: Anthropometric measurement and indices

Nutritional anthropometry is concerned with the measurement of the variation of the physical dimensions and the gross composition of the human body at different age levels and degrees of nutrition (Jelliffe, 1966). It is relatively an easy technique to employ, as it is non-invasive and applicable to situation where large size samples are involved (Johnston, 1981) and requires minimum equipment compared to biochemical techniques. Data on somatic measures such as height, weight (Jelliffe, 1966) were obtained for all the subjects.

3.6.2.1: Height: Height is a measure of linear growth of the body and degree of skeletal development. It is primarily a reflection of cumulative or past nutritional status (Jelliffe, 1966). Height was measured using height scale in cm. The subject was made to stand on the platform straight and upright, bare foot with the heels, shoulders and back of the head upright and touching the stand. Standing on a higher platform (so that height can be measured accurately to the eye level), the head piece was gradually moved, until it rested on the head in the center (without applying pressure) and the height was read to the nearest of 0.1 cm.
3.6.2.2: **Weight**: Weight is a measure of total body mass and is sensitive indicator of current nutritional status. Weight of the subjects were recorded with minimum clothing and without shoes to the nearest tenth of a kilogram (0.1 kg) using electronic weighing scale. The accuracy of weights was ascertained by using standard weight. The zero adjustments of the scale was checked prior to each measurement (Jelliffe, 1966).

A minimum of three readings were recorded and the mean calculated.

3.6.2.3: **Stature for age and weight for age percentiles**: The height and weight percentiles of subjects were calculated using growth charts of Indian Pediatrics. The percentiles are standards for height and weight as per growth charts (Annexure V11). The children were classified based on their percentiles as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentile Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undernourished</td>
<td>Less than 5th percentile</td>
</tr>
<tr>
<td>Normal</td>
<td>5th percentile to less than 85th percentile</td>
</tr>
<tr>
<td>Overweight</td>
<td>85th to less than 95th percentile</td>
</tr>
<tr>
<td>Obese</td>
<td>Equal or greater than 95th percentile</td>
</tr>
</tbody>
</table>

3.6.2.4: **Body Mass Index (BMI) percentiles**: BMI is a number calculated from a child's weight and height, a reliable indicator of body fatness of children and teens. BMI is defined as weight in kilograms divided by square of the height in meters (Mahatab S Bamji, 1998 and NIN, 1999).

The BMI is calculated using the following formula:

\[
\text{Body mass Index (BMI)} = \frac{\text{Weight (kg)}}{\text{Height (m}^2\text{)}}
\]

BMI number is plotted on the gender based BMI-for-age growth charts of Indian pediatrics to obtain a percentile ranking. Percentiles are the most commonly used indicator to assess the size and growth patterns of individual children. The percentile indicates the relative position of the child's BMI number among children of the same sex and age. BMI is used as a screening tool to identify possible weight problems for children. Agarwal and the Indian Academy of Pediatrics (IAP) recommend the use of
BMI to screen for overweight and obesity in children beginning at 2 years old. Based on the BMI percentiles the subjects are categorized according to the standards. BMI-for-age weight status categories and the corresponding percentiles are shown in the following Table:

<table>
<thead>
<tr>
<th>Weight Status Category</th>
<th>Percentile Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>Less than 5th percentile</td>
</tr>
<tr>
<td>Healthy weight</td>
<td>5th percentile to less than 85th percentile</td>
</tr>
<tr>
<td>Overweight</td>
<td>85th to less than 95th percentile</td>
</tr>
<tr>
<td>Obese</td>
<td>Equal or greater than 95th percentile</td>
</tr>
</tbody>
</table>

3.7: CLINICAL PARAMETERS AND BIOCHEMICAL ESTIMATIONS

3.7.1: Blood Pressure Level

Left arm systolic (SBP) and diastolic (DBP) blood pressure were taken from each study subject with the periodically calibrated mercury sphygmomanometer. Blood pressure from all 132 study subjects were recorded. Two BP measurements were taken and averaged for analysis. A third measurement was only taken when the difference between the 2 measurements was $\geq 5$ mmHg, and subsequently, the mean was calculated and compared with the normal values. A 5-minute relaxation period between measurements was maintained throughout the study.

3.7.2: Blood Glucose Level

The prescribed blood sugar tests to determine the glucose level in the blood are Fasting Blood Sugar (FBS), Post-Prandial Blood Sugar (PPBS) and Glucose Tolerance Test (GTT).

**FBS** - The blood test is performed after twelve hours of fasting. The person must refrain from eating approximately 12 hours prior to this blood test.
PPBS – Prior to this test, the person fasts overnight and then consumes a meal. Approximately 1 1/2 to 2 hours after eating, a blood sample is drawn for testing.

GTT – The test is performed after consuming a concentrated amount of glucose dissolved in water.

Home Monitoring Blood Glucose (HMBG) refers to the ongoing measurement of blood sugar (glucose). The subjects and their parents were trained to measure blood glucose levels using portable device (glucometer). The glucometers used by the individual subjects were calibrated by the company representatives before starting the study in both the hospitals. There are many different kinds of glucometers and all work essentially the same way. The mean blood glucose levels of fasting and post prandial were calculated based on three consecutive days reading and compared with normal standards stipulated for the children age wise (American Diabetic Association, 2010) (Annexure VIII & IX).

3.7.3: Glycosylated Heamoglobin Levels (HbA1c)

Determination of haemoglobin A1c provides an important diagnostic tool for monitoring the efficiency of dietary control and therapy during treatment of diabetes mellitus since, long term treatment of the disease emphasizes the importance of control of blood glucose levels in preventing the acute and chronic complications of diabetes. The blood samples of the study subjects were drawn in the hospital by the phlebotomist and analyzed for HbA1c values and compared with standard values (Annexure XI).

3.8: CALCULATION OF INSULIN DOSAGE

This includes both basal (intermediate/long acting) and bolus (short/rapid acting) insulin.

- Basal insulin is continuous, background insulin which can be either intermediate or long acting that the body needs to keep blood sugar in control when no food is eaten. Basal insulin requires even during periods of sleep.
- Bolus insulin is extra insulin that is released as needed to match the amount of carbohydrate that is eaten in the food. Bolus insulin will also be given to bring down high blood sugars.

3.8.1: Calculation of total dosage including both basal and bolus insulin based on the body weight (Diabetes Teaching Center, University California, 2012).

One unit of insulin per kg body weight of the child

3.8.2: Calculation of bolus insulin dosage as per CHO intake (American Diabetes Association, 2010).

1st Step: Insulin to carbohydrate ratio = 1 unit of insulin per 15 gms of carbohydrate divide the total carbohydrate in the meal by 15 gms = Total units of insulin

Ex: A meal providing 60 gms of CHO require, 60 divided by 15 = 4 units of insulin.

2nd Step: Blood glucose correction factor

a). Subtract Target Blood Glucose level (TBG) from Pre Meal Blood Glucose level (PMBG).

\[240 \text{ mg/dl (PMBG)} - 140 \text{ mg/dl (TBG)} = 100 \text{ mg/dl}\]

b). 1 unit of insulin is required for every 50 mg/dl of blood glucose levels above the target pre meal blood glucose level.

1 unit of insulin for 50 mg/dl and therefore 2 units for 100 mg/dl

3rd Step: Total amount of bolus insulin required for the meal is Step1 + Step 2

4+ 2 = 6 units

3.9: QUALITY OF LIFE

The quality of life of the subjects was measured using the EQ-5D. EQ-5D, a standard measure of health status for children developed by the Euro-Qol group in order to provide a simple, generic measure of health for clinical and economic appraisal. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care as well as population surveys (Annexure VI).
3.10: NUTRITIONAL EDUCATION (INTERVENTION STUDY)

81 subjects from the total study sample above the age group of 10 years were selected for the intervention study. A follow up for a period of 3 months was done to develop a rapport and to convince them to participate in the intervention program. A booklet titled “Children with Diabetes- Can we lead a normal life” was prepared and given to all the subjects to facilitate the intervention programme. Booklet model is given in annexure XIII. A detailed version of intervention program is depicted in Annexure XII. At the end of 3 months information pertaining to the different variables was collected. Research design pertaining to the intervention study is depicted in the form of a flow chart.
3.10.1: INTERVENTION PROGRAMME

INSTITUTIONS

Sagar Hospitals, (SH) (n=23)

Indira Gandhi Institute of Child Health (IGICH) (n=58)

SELECTION OF THE SUBJECTS (n= 81)

3 MONTHS FOLLOW UP AND COLLECTION OF DATA

ANTHROPOMETRIC MEASUREMENTS

DIETARY ASSESSMENT

BLOOD GLUCOSE LEVELS

INSULIN INTAKE

QUALITY OF LIFE ASSESSMENT

INSULIN DOSE

INTERVENTION PROGRAMME SCHEDULE

GROUP COUNSELLING

3 sessions in 3 months

INDIVIDUAL COUNSELLINGS

2 sessions in 3 months

REASSESSMENT

AFTER 12 WEEKS (n=40)

Anthropometric Measurements

Life-style Assessment

Dietary Assessment

Blood Glucose, HbA1c, Insulin Intake

Quality of Life

Insulin Dose

ANALYSIS AND INTERPRETATION OF DATA

PRESENTATION OF DATA
3.11: STATISTICAL ANALYSIS

Descriptive statistical analysis has been carried out in the present study. Inferential statistical tests like independent sample t-test, chi-square test and Mann-Whitney u test were used to elicit information from the data. Results on continuous measurements were presented as mean ± SD (Min-Max) and results on categorical measurements were presented in number (%). Significance was assessed at 5 % level of significance. Student ‘t’ test (two tailed, paired) has been used to find the significance of study parameters on continuous scale (between two groups Inter group analysis) on metric parameters.

**STUDENT T TEST (TWO TAILED, PAIRED)**

\[
    t = \frac{\Sigma d}{\sqrt{\frac{n(\Sigma d^2) - (\Sigma d)^2}{n-1}}}
\]

Where \(d = x_{1i} - x_{2i}\)

\(x_{1i}\) are observations from first sample and \(x_{2i}\) are observations from second sample and \(n\) represents number of observations in the sample.

**Chi square for independent of attributes:**

\[
    \chi^2 = \Sigma \frac{(O - E)^2}{E}
\]

Where \(O\) = the frequencies observed

\(E\) = the frequencies expected


**Significant figures:**

Statistically Significant at 95% confidence level (p<0.05)

Suggestive Significant  *  p >0.05

Moderately Significant  **  p ≤0.05

Strongly Significant  ***  p ≤ 0.001

**Statistical software**

The Statistical software namely SPSS 17.0, Stata 10.1, Med Calc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs and tables.

---

Page 50