Chapter 3
Materials & Methods
MATERIALS AND METHODS

This study was conducted after obtaining approval from the Institutional Ethics Committee of Sri Ramachandra University (Ref: IEC/10/JAN/79/05) (Enclosure 1).

The detailed methodology used to carry out the study is presented in this section under the following headings:

3.1 Research design
3.2 Sample size
3.3 Sampling design
3.4 Criteria for sample selection
3.5 Period of study
3.6 Universe and brief description of the setting
3.7 Detailed Methodology
3.8 Statistical analysis

3.1. RESEARCH DESIGN

A prospective observational study design was adopted to carry out the study. Prospective study is one which moves forward in time from the cause to the effect. It is also known as follow-up study.

Unlike retrospective study, a prospective study is able to estimate relative risk, since the sampling fractions of the cases and controls are known. The principal use of this study is in the elucidation of aetiology. It enables the
investigator to obtain accurate information about the individuals before the onset of disease being investigated while providing unique information about the natural history of disease. This study design also allows more rigorous testing of aetiological hypothesis than other observational studies (Kothari C.R., 2007).

3.2. SAMPLE SIZE

This refers to the number of items to be selected from the universe to constitute a sample. The size of sample should be optimum. An optimum sample is one which fulfils the requirements of efficacy, representativeness, reliability and flexibility.

The sample size for the study was calculated using the PS- power sample size calculator and arrived at a size of 260 subjects to be studied during the study period. (Sample size calculation Enclosure 2)

3.3. SAMPLING DESIGN

Sampling is a process, which helps to identify the characteristics of the universe of population or a population by studying only a part of it (Kothari C.R., 2007). The process of selecting the samples or respondents is called sampling technique.

The study involved collection of data from all the subjects admitted to the PICU based on the inclusion and exclusion criteria during the study period and hence a particular sampling design was not used to identify the samples.
3.4. CRITERIA FOR SAMPLE SELECTION

The criteria that were followed for selection of study subjects are as follows:

Inclusion criteria

➢ Subjects who are admitted in the PICU
➢ Subjects with PICU length of stay 72 hours or longer
➢ Subjects between the age group of > 28 days to six years
➢ Subjects who are on Oral nutrition support and Oro/nasoenteric feeding

Exclusion criteria

➢ Subjects on Total Parenteral Nutrition (TPN) support
➢ Subjects whose accurate admission body weight could not be taken

3.5. PERIOD OF STUDY

The study was conducted for a period of two years from January 2010 to December 2011 (data collection – one and a half year, analysis and write up – six months).

3.6. UNIVERSE AND BRIEF DESCRIPTION OF THE SETTING

Subjects were selected from the 16 bedded multispecialty tertiary care Paediatric Intensive Care Unit (PICU) at Sri Ramachandra Medical Centre and Hospital located at Porur, Chennai, India, a private self- financing institution, dedicated to serve the society as a centre of excellence with emphasis on medical education, research and health care.
DATA COLLECTION TOOL

Demographic Data, Family History, Medical History of the subject was collected using an interview schedule from the care takers of the study subjects and medical records (Enclosure 3). Subjective Global Assessment tool was used for nutritional screening.

3.7. DETAILED METHODOLOGY

Demographic data of the subjects specifically age and sex was collected from their respective medical records.

Medical History details such as diagnosis and history of presenting illness were obtained from their respective medical records.

Nutritional assessment is important in children because undernutrition is the single most important cause of growth retardation. Severe malnutrition during critical illness can result in suboptimal organ growth or function. All the children should receive nutrition assessment within one to five days of paediatric intensive care admission (Matarese L.E., 2007). Nutrition screening, unlike assessment, identifies children who at risk for malnutrition or already malnourished.

Nutritional assessment of the subjects was done using the universally accepted ABCD method i.e. Anthropometric measurements, Biochemical data, Clinical Evaluation and Dietary information upon admission to the paediatric intensive care unit.
Anthropometric measurement deals with the measurement of size, shape, weight and proportions of human body.

In our study, anthropometric measurements such as height, body weight, head and chest circumference (≤ 2 years) and mid upper arm circumference (1-5 years) were taken.

**Height**: Height of a child is an indicator of his/her past nutritional status. It is relatively insensitive to rapid changes in nutritional status. It is a good indicator of the chronicity of any deliberating illness.

In our study, for children up to 24 months and those children who were not able to stand, the recumbent length was measured using a flexible inch tape. Two examiners were required to correctly position the subject and ensure accurate and reliable measurements of length. The head and the foot end was marked using a wooden board and then the distance between the two was measured to the nearest 0.1 centimeter. The height of the children over two years of age and those who were able to stand was measured in the standing position using a stadiometer. While measuring height, the subject was made to stand straight with the head positioned such that the frankfurt plane is horizontal, feets together, knees straight and heels, buttocks, shoulder blades in contact with the vertical surface of the stadiometer and arms hanging loosely at the sides with palms facing the thighs and the height was measured to the nearest 0.1 centimeters as shown in plate 1.
PLATE 1: MEASUREMENT OF LENGTH AND HEIGHT

The assessed height was compared with the expected height using reference standards (Agarwal D.K. et.al., 1994) which is considered as the best choice by IAP guideline group for growth monitoring of Indian children and was interpreted with Waterlow’s classification for height for age as shown in table 3.1

Table 3.1: Waterlow's Classification

<table>
<thead>
<tr>
<th>Waterlow’s Classification</th>
<th>Height for age (% of expected)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&gt;95</td>
</tr>
<tr>
<td>Mild Stunting</td>
<td>90-95</td>
</tr>
<tr>
<td>Moderate Stunting</td>
<td>85-90</td>
</tr>
<tr>
<td>Severe Stunting</td>
<td>&lt;85</td>
</tr>
</tbody>
</table>

**Body Weight:** It is the most frequently used and important anthropometric measurement. Body weight recording is essential for assessing the growth of the child and his/her nutritional status, important for planning the diet, for follow up of the child especially while recuperating from an illness or during nutritional rehabilitation (Koletzko B. *et.al.*, 2008).

In our study, for children up to 24 months, the body weight was checked using a weighing pan with no clothing. The body weight of children over two years, was checked using a calibrated electronic weighing machine with light clothing as shown in plate 2.
The assessed body weight was compared with the expected weight using reference standards (Agarwal D.K.et.al.,1994) and was interpreted with IAP Classification for weight for age and Waterlow's classification for weight for height to understand the extent of malnutrition or adequacy of nutritional status as presented in table 3.2 (a) (b).

**Table 3.2 (a): IAP Classification**

<table>
<thead>
<tr>
<th>IAP Classification</th>
<th>Weight for age (% of expected)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&gt;80</td>
</tr>
<tr>
<td>First degree PEM</td>
<td>71 -80</td>
</tr>
<tr>
<td>Second degree PEM</td>
<td>61-70</td>
</tr>
<tr>
<td>Third degree PEM</td>
<td>51-60</td>
</tr>
<tr>
<td>Fourth degree PEM</td>
<td>&lt;50</td>
</tr>
</tbody>
</table>


**Table 3.2 (b): Waterlow’s Classification**

<table>
<thead>
<tr>
<th>Waterlow’s Classification</th>
<th>Weight for height (% of expected)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&gt;90</td>
</tr>
<tr>
<td>First degree wasting</td>
<td>80 -90</td>
</tr>
<tr>
<td>Second degree wasting</td>
<td>70-80</td>
</tr>
<tr>
<td>Third degree wasting</td>
<td>&lt;70</td>
</tr>
</tbody>
</table>


**Head Circumference:** The size of the head is a good indicator of the past and current malnutrition during fetal life and early childhood. With the help of
a non-stretchable inch tape the occipital frontal head circumference from the external occipital protuberance to the glabella was measured to the nearest 0.1 cm in children up to two years as shown in plate 3.

Measured values below the standards were considered as low. Standards are as shown in table 3.3.

**Table 3.3: Standards for Head Circumference**

<table>
<thead>
<tr>
<th>Age</th>
<th>Head Circumference (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Boys</td>
</tr>
<tr>
<td>3 months</td>
<td>40.6</td>
</tr>
<tr>
<td>6 months</td>
<td>43.8</td>
</tr>
<tr>
<td>9 months</td>
<td>45.8</td>
</tr>
<tr>
<td>1 year</td>
<td>47.0</td>
</tr>
<tr>
<td>2 year</td>
<td>49.2</td>
</tr>
</tbody>
</table>

Source: Agarwal DK, Agarwal KN. Physical growth in Indian affluent children (Birth – Six years). Indian Paediatrics. 1994; 31, 377-413

**Chest Circumference:** The Chest circumference was measured at the level of the nipples, midway between inspiration and expiration to the nearest 0.1 cm using a non-stretchable inch tape in children up to two years as shown in plate 3.

Measured values below the standards were considered as low. Standards are as shown in table 3.4.
Table 3.4: Standards for Chest Circumference

<table>
<thead>
<tr>
<th>Age</th>
<th>Chest Circumference (cm)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Boys</td>
<td>Girls</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>38.4</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>42.0</td>
<td>41.6</td>
<td></td>
</tr>
<tr>
<td>9 months</td>
<td>44.1</td>
<td>43.7</td>
<td></td>
</tr>
<tr>
<td>1 year</td>
<td>45.4</td>
<td>45.0</td>
<td></td>
</tr>
<tr>
<td>2 year</td>
<td>49.0</td>
<td>48.4</td>
<td></td>
</tr>
</tbody>
</table>

Source: Agarwal DK, Agarwal KN. Physical growth in Indian affluent children (Birth – Six years). Indian Paediatrics. 1994; 31, 377-413.

PLATE 3: MEASUREMENT OF HEAD AND CHEST CIRCUMFERENCE
Mid Arm Circumference (MAC): It is a simple, cheap and easy method of detecting somatic protein and fat stores and to identify “at risk” children. Mid arm circumference is constant between 1-5 years of age.

The measurement of circumference of the arm at the midpoint between the acromion and the olecranon with the arm hanging by the side of the body was recorded to the nearest 0.1 cm in children aged one to five years using a non stretchable inch tape as shown in plate 4. It was interpreted as presented in table 3.5

<table>
<thead>
<tr>
<th>Values</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.5 cm to 17 cm</td>
<td>Normal</td>
</tr>
<tr>
<td>12.5 cm to 13.5 cm</td>
<td>Mild Malnutrition (at risk)</td>
</tr>
<tr>
<td>&lt; 12.5 cm</td>
<td>Moderate to Severe Malnutrition</td>
</tr>
</tbody>
</table>

Source: Gupte S, Textbook of Pediatric Nutrition, Peepee Publications, 2006, Pg no. 31
**Body Mass Index (BMI):** It correlates well with the subcutaneous fat and the total body fat and yet allows a variation in the lean body mass. It was calculated in children aged two to six years using the following formula:

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

It was interpreted using the WHO 2007 standards as shown in table 3.6.

**Table 3.6: BMI Interpretation**

<table>
<thead>
<tr>
<th>Values</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median -2SD to + &lt;1SD</td>
<td>Normal</td>
</tr>
<tr>
<td>Median &lt;-2SD to &gt; -3SD</td>
<td>Moderate Malnutrition</td>
</tr>
<tr>
<td>Median &lt; -3SD</td>
<td>Severe Malnutrition</td>
</tr>
<tr>
<td>Median ≥ +1SD to &lt; 3SD</td>
<td>Overweight</td>
</tr>
<tr>
<td>≥ + 3SD</td>
<td>Obesity</td>
</tr>
</tbody>
</table>

Anthropometric measurement (body weight, height, mid arm circumference, head and chest circumference) was assessed within 24 hours of admission in all children admitted to the paediatric intensive care unit and then body weight was rechecked at discharge.

*z* scores for W/A, W/H and H/A were calculated using the following formula:

**WAZ:** \([\text{observed weight - median weight (same age and sex)}] / \text{standard deviation}\)

**WHZ:** \([\text{observed weight - median weight (same height and sex)}] / \text{standard deviation}\)

**HAZ:** \([\text{observed height - median height (same age and sex)}] / \text{standard deviation}\)
The calculated ‘z’ scores were interpreted using WHO classification (2007) as follows:

<table>
<thead>
<tr>
<th>Values</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median -2SD to + &lt;2SD</td>
<td>Normal</td>
</tr>
<tr>
<td>Median &lt;-2SD to &gt; -3SD</td>
<td>Moderate undernutrition</td>
</tr>
<tr>
<td>Median &lt; - 3SD</td>
<td>Severe undernutrition</td>
</tr>
</tbody>
</table>

**Subjective Global Assessment**

Subjective Global Assessment tool is an alternative method of nutritional assessment based exclusively on a carefully performed medical history and physical examination. It is a reliable and a valid method to assess nutritional status in hospitalized patients. However, evidence regarding its usefulness in critically ill children is lacking. But, based on the few documented study regarding (Rojratsirikul C. *et al.*, 2004; Dogan Y. *et al.*, 2005; Secker D.J. *et al.*, 2007) its usefulness in assessing the nutritional status in various clinical settings, the SGA tool was used for assessing the nutritional status of children admitted to the paediatric intensive care unit within 24 hours of admission.

This technique uses five features of medical history. Weight loss less than five percent is considered as a small loss, between five percent to 10% a potentially significant loss and > 10% a definitely significant loss. Dietary intake relative to the patient’s usual pattern is the second feature. Patients are classified as having normal or abnormal intake with the duration and degree
of abnormal intake was also noted. The third feature is the significant gastrointestinal symptoms such as anorexia, nausea, vomiting and diarrhea. Symptoms that have persisted on virtually a daily basis for longer than two weeks would be considered significant. The fourth and fifth features of history are the patient’s functional capacity or energy level and the metabolic demands of the patient’s underlying disease, respectively.

There are four features of the physical examination that are noted as either normal, mild, moderate or severe. These include loss of subcutaneous fat, muscle wasting and ascites. In this tool no anthropometric and laboratory indices were included.

Subjective global assessment tool (SGA) was administered to reliable mother/father of the children and answers to the tool were sought through personal interview method. A three point scoring system was applied to the above variables. On the basis of these features the subjects were categorized into well nourished (score 1-11), moderately malnourished (score 12-22) and severely malnourished (score 23-33) categories.

SGA categories were compared with IAP weight for age (W/A) criteria for malnutrition to check the usefulness of this tool for routine nutritional assessment in children admitted to the paediatric intensive care unit.
Biochemical parameters

**Haemoglobin** - Anemia is a common problem in critically ill patients admitted to intensive care units (ICUs). Deleterious effects of anemia include increased risk of cardiac related morbidity and mortality as well as a generalized decrease in oxygen carrying capacity. Therefore, diagnosing anemia by measuring the hemoglobin levels of patients in hospital is essential.

Haemoglobin values of the subjects were noted from the laboratory assessment documented in their respective medical records to understand their level of nutritional status. The normal value for children is > 11 gm/dl.

It was interpreted as follows:

- >11.0g/dl : Normal
- 10-10.9 : Mild Anemia
- 7-9.9 g/dl : Moderate Anemia
- <7.0g/dl : Severe Anemia (WHO,2011)

**Total Lymphocyte Count** – Total lymphocyte counts are clinical measures of immune function that reflects B cells and T cells and are used as screening or assessment parameters.

It was calculated using the following formula

\[
TLC = \frac{\% \text{ Lymphocyte} \times \text{White blood cells (WBC)}}{100}
\]
It was interpreted as follows:

1500-1800 mm³ : Mild depletion

900-1500 mm³ : Moderate depletion

<900 mm³ : Severe depletion (Hopkins B., 1993)

**Albumin** - It is the protein found in the highest concentration in blood, making up over half of the protein mass. Albumin has a half-life in blood of about three weeks and decreased levels are not seen in the early stages of liver disease. Albumin values of the patients were noted from the laboratory assessment documented in their respective medical records. Normal albumin levels should be between 3.5 and 5.5 g/dl.

It was interpreted as follows:

2.8-3.5 g/dl : Mild depletion

2.1-2.7 g/dl : Moderate depletion

<2.1 g/dl : Severe depletion (Hopkins B., 1993)

**Nutrition Support**

Nutritional support is a routine part of the care of critically ill patients and it is now widely accepted for the treatment and prevention of malnutrition and specific nutrient deficiencies. It is also generally assumed to improve outcome, as with most other forms of treatment (Webster N.R. et al., 2000).

Most of the subjects in our study were prone to develop nutritional risk due to their underlying medical illness and therefore had special nutritional needs.
Their respective nutritional requirements were determined based on their illness and their nutritional status at admission.

**Estimation of Nutritional requirements:** Estimation of requirements was carried out for different age groups on an individual case basis, based on the ICMR recommendations (2009) which were also comparable to the international standards for critically ill children (Mehta N.M, 2009) as shown in table 3.7.

**Table 3.7: Nutrient Estimation**

<table>
<thead>
<tr>
<th>Age</th>
<th>Kilocalories/kg</th>
<th>Protein/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6 months</td>
<td>108</td>
<td>2.2</td>
</tr>
<tr>
<td>6-12 months</td>
<td>98</td>
<td>1.6</td>
</tr>
<tr>
<td>1-3 years</td>
<td>102</td>
<td>1.2</td>
</tr>
<tr>
<td>4-6 years</td>
<td>90</td>
<td>1.1</td>
</tr>
</tbody>
</table>


**Fluid and Micronutrients:** The fluid estimation was done using the Holiday and Segar Formula based on the actual weight of the subject. The micronutrients (vitamins and minerals) were given according to ICMR recommendations (Enclosure 4). Micronutrient intake could be achieved through the provision of optimal nutrition support using breast milk, artificial formulas and oral soft solid diet.
Administering Nutrition: Having assessed the baseline nutritional status and requirements of a child in the paediatric intensive care unit, the next step was to actually deliver the nutrients.

Route of Nutritional Support- Practicing established standards of optimal nutrition assessment and nutrition support protocols will assure patients receive estimated requirements in a timely manner. The subjects in this study were initiated with either oro/nasoenteric feeds or were fed orally based on their clinical condition, level of consciousness and ability to take oral feeds.

**Figure 3.1: Routes of Nutrition Support**

Oral feeding was preferred in unintubated subjects who are alert with optimal cough and gag reflexes. In intubated subjects, oro/nasoenteric feeds was provided, usually as an intermittent bolus. For those who were in a position to resume oral nutrition support after the initial phase of hemodynamic stabilization, breast milk, nutrient dense formulas and/or progressive hospital diets in terms of modified consistency starting from clear liquids and progressing to soft solids was suggested, without compromising the nutritional intake. Subsequently, an individualized nutrition care plan was devised. Dietary manipulation, the use of dietary
supplements and assistance with feeding were adopted depending on the case with care taken to meet the estimated nutrient requirement.

Oro/nasoenteric feeds was provided using various formulas as explained below.

- Subjects < 2 years of age on oro/nasoenteric feeds, the estimated requirement was met using expressed breast milk or standard infant formula.
- For subjects > 2 years of age standard paediatric enteral formulas were used (Enclosure 5).

**Protocol for Oro/nasoenteric feeding**

**Initiation of feeds:** The optimal time to administer nutrition to an infant or child in the paediatric intensive care unit may differ from one centre to another. Assuming that the nutritional stores are already depleted, some authors have suggested initiation of feeds in these children within a few days in infants, within five days in older children and within seven days in adolescents. In this study, once the patient was resuscitated and stabilized in the intensive care setting, feeds were initiated in consultation with the admitting physician within 24-72 hours of ICU admission. The day on which the nutrition support was started was considered as the day of initiation of nutrition support irrespective of the day of admission.
**Advancement of feeds**: Once having started on tube feeds, it is essential to advance the feed rate to enable achievement of goals within one to four days after initiation of feeds.

In this study, the calorie and protein intake of each subject on tube feeds was calculated and to meet the deficit, gradual advancement of feed rate by 25% of the previously tolerated volume was done every two to four feeds to meet the goal rate. The day on which the patient was able to meet 100% of the requirements was considered as the day of attainment of goals. The initiation and progression of the nutrition support was carried out as per the PICU guidelines of oro/nasoenteric (bolus) feeding as presented in the following table 3.8.

**Table 3.8: Initiation and Advancement Rates**

<table>
<thead>
<tr>
<th>Goal Rate of feeding</th>
<th>Total volume of fluids (calculated using Holiday and Segar formula) to be given (subtract IV fluid volume, if any) divided by 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation Rate</td>
<td>50% of the estimated goal rate of feeding</td>
</tr>
<tr>
<td>Advancement Rate</td>
<td>25% of the previously tolerated rate, every two to four feeds</td>
</tr>
</tbody>
</table>

Measurement of gastric residual volumes (GRVs) was done routinely to assess enteral feed tolerance. Current opinion suggests that a GRV > 5ml/kg can be considered to be an indicator of poor feed tolerance and delayed gastric emptying (Zaloga G.P. *et al.*, 1997). In case of intolerance, feeds were
withheld for two hours and then rechecked for GRV. Then, if GRV is < 5ml/kg, feeds were restarted at the previously tolerated rate and feed rate was increased till the target rate of feeds was reached.

**Transition of feeds:** Management of transition from oro/nasoenteric feeding to oral intake requires careful management. As soon as the patient was alert and able to manage the mechanics of chewing and swallowing, the transition phase of tube feeding was started. When voluntary intake approached 60% of nutrient requirements for more than two or three consecutive days, oro/nasoenteric feedings were either slowed, or the number of feedings was progressively decreased till the subject was totally dependent on oral nutrition support.

**Monitoring**– Baseline acquisition of monitoring parameters aids in the determination of tolerance and adequacy of therapy and individual substrates. In this study, the subjects were followed up/monitored on a day to day basis until discharge from the hospital for nutrient intake in terms of energy, protein, carbohydrate and fat intake, biochemical monitoring, anthropometric changes in terms of weight, intake and output and gastrointestinal complications through documentation of abdominal distension, diarrhea, vomiting etc.

For subjects receiving Demand Breast feeds, the child was weighed before and after feeds, then an average intake for a day was considered and the nutrient count was done (Elizabeth K.E, 2007).
Nutritional status at discharge was reassessed using the subjective global assessment tool. The differences in the initial and final categories of nutritional status were analyzed to understand the impact of protocolized nutritional support in this cohort.

**Length of Stay:** Length of stay in the hospital was considered from the day of admission of the patient to the hospital till the patient was discharged from the hospital.

**Ventilation Support days:** Ventilation Support days of the patients, if any, was considered from the day of intubation till the day of extubation.

**Feeding Interruptions:** Although importance of nutrient delivery in hospitalized subjects is well recognized, barriers to optimal delivery of nutrients at the bedside still persist. The care of a critically ill patient involves multiple interventions, which often compete with the delivery of nutrients in the intensive care setting. Elective procedures, unplanned interventions, or diagnostic tests often require a fasting state, requiring interruption of nutrition support. In addition, feed intolerance or contraindications to feeding related to the disease processes may require feeding to be postponed or discontinued in the PICU. All these factors may contribute to suboptimal nutrient administration in the PICU.

As the study involved subjects in the critically ill set up and as has been reported by many studies, the interfering factors for reaching the estimated
nutrient goal such as endotracheal intubation and extubation, diagnostic tests or procedures in the radiology suite, other procedures at the bedside, feeding tube malfunction, malposition or obstruction, gastric aspirations were noted during the follow up period.

The impact of these feeding interruptions on nutrient delivery and other outcomes (listed below) were also noted during the follow up period.

- Nutrient Intake
- Timeliness of Enteral Nutrition Support (day of attainment of goals)
- Weight changes
- Changes in biochemical parameters
- Length of Hospital Stay

The overall impact of early (≤2 days) versus delayed (>2 days) nutritional support on clinical outcomes in all the children admitted in the paediatric critical care unit was assessed. Then, comparison of clinical outcomes in children without feeding interruption versus those with any feeding interruption was also done.
OVERALL METHODOLOGY

Nutritional status assessment

Estimating the nutritional requirements, initiating and management of nutrition support (Oral and/or Oro/nasoenteric feeds)

Follow—up on day to day basis

Assessing the Outcomes of Nutritional Support in terms of the following

- Nutrient Count
- Weight changes
- Biochemical Parameters
- Gastrointestinal Complications
- Ventilation Support days
- Length of stay
- Feeding Interruptions

Reassessment of Nutritional Status
3.8. STATISTICAL ANALYSIS

Statistical techniques are used for describing and finding relationships among variables.

Statistical analysis was performed with the use of Scientific Package for Social Sciences (SPSS) version 16.0. The results are reported as descriptive statistics and inferential statistics. The tests that analyzed the data statistically under the two categories are explained below:

1) **Descriptive Statistics:** It is an analytical procedure to describe and summarize the characteristics of the subjects. In this study, the tools used for descriptive analysis are as follows:

   a) **Percentages, Bar graphs:** These are designed to show different values in a more easier and precise format.

   These tools were used to describe the general characteristics of the study subjects such as Gender and Age classification, Distribution of subjects based on clinical condition, IAP Classification, Waterlow’s Classification, BMI Categories, SGA Categories, Routes of Nutritional Support, Timeliness of Nutritional Support, Biochemical parameters, Gastrointestinal Complications, Ventilator support days and Feeding Interruptions.
b) **Mean and Standard deviations**: was used to describe the anthropometric profile, biochemical parameters, recommended nutrient intake, timeliness of Nutritional Support, actual nutrient intake, length of Stay and ventilation support days of the subjects in the hospital.

2) **Inferential Statistics**: These are tests which are used to draw inferences about a population from a sample. In this study, the tests which were used for inferential analysis to compare continuous variables are as follows:

a) **Student’s ‘t’ –test**: It determines whether a difference exists between the means of two independent populations. In this study Student’s ‘t’ –test was used to assess the impact of early nutrition support and feeding interruptions on nutrient delivery, timeliness of nutritional support, weight changes, biochemical parameters and length of hospitalization in paediatric subjects admitted in an intensive care unit.

b) **Chi- Square analysis**: It is a non parametric test used for the data that are frequency counts in categories. In this study, Chi square analysis was done to compare the differences between the initial and final SGA categories and thus the effect of nutrition support on the nutritional status.

c) **Sensitivity and Specificity**: It is a tool to assess the diagnostic accuracy.

    Sensitivity and Specificity of Subjective Global Assessment has been
compared against IAP weight for age (W/A) criteria for malnutrition to check the usefulness of this tool for routine nutritional assessment in paediatric patients admitted in an intensive care unit.

3) **Level of Significance:** Significance levels show how likely a result is due to chance. In our study, statistical significance was set at p-values less than 0.05, 0.01 and 0.001. All reported p-values were two-sided.