A Study Evaluating The Efficacy Of A Home Based Intact Polymeric Formula In The Nutritional Management Of Critically Ill Patients

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ABSTRACT

Background and Objective: Malnutrition is prevalent to a high degree among hospitalized patients throughout the world. As many as 40% of the adult patients are seriously malnourished at their hospital admission, and two thirds of all patients experience deterioration of their nutritional status during their hospital stay. India, with its nearly 1 billion inhabitants, has an estimated 350-400 million people below the poverty line, 75 per cent of them in the rural areas. Meeting the nutritional requirements of all those under such conditions is a daunting task. Sri Ramachandra University Hospital caters to the needs of people from different socio economic backgrounds and there has been a constant approach in meeting the nutritional requirements of all, irrespective of their socio economic status. A home based intact polymeric formula is being used for more than a decade to meet the nutritional requirement of the patients at the free Inpatient block of the hospital, where patients from poor economical backgrounds are admitted and treated. There has been no documented complaint of any gastrointestinal complication due to the intact polymeric formula, contrary to the published reports by various authors in their research carried out in different hospital settings. Hence, this present study was undertaken to prove the efficacy of this home based intact polymeric formula in the nutritional management and recovery of critically ill patients, while maintaining the safety standards. Design: A prospective study design was adopted to carry out the study. A total of 30 subjects were studied between the study period from January'09 to March'09. There were 15 subjects each in the two study groups (Patients who were administered the home based Intact polymeric formula and the standard Commercial formula). These patients were followed up for various outcome variables such as nutrient intake, length of stay in the ICU, gastrointestinal complications, duration of mechanical ventilation and feed costs. Results: Despite receiving different types of formulas, the nutrient intake, length of stay in the ICU and the duration of mechanical ventilation were not significantly different in the two study groups. There was a significant ($p<0.05$) difference in the feed costs which were incurred to the patients who were fed with both the formulas. Conclusion: It is inferred from this study, that the home based intact polymeric formula is comparable to the standard commercial formulas, if the formula is planned with nutritionally adequate components, reconstituted adequately and implemented as per the protocols, in improving the expected clinical outcome in the critically ill patients.

Key Words: Malnutrition, Home based intact polymeric formula, Standard commercial formula, Clinical outcome

INTRODUCTION

Malnutrition is prevalent to a high degree among hospitalized patients throughout the world [1]. As many as 40% of the adult patients are seriously malnourished at their hospital admission and two thirds of all the patients experience deterioration of their nutritional status during their hospital stay. A nutritionist's role in the hospital is to formulate the most appropriate nutritional therapy for each patient, based on their nutritional status. Sri Ramachandra University Hospital caters to the needs of people from different socio economic backgrounds and there has been a constant approach in meeting the nutritional requirements of all, irrespective of their socio economic status. A home based intact polymeric formula is being used for more than a decade to meet the nutritional requirement of the patients at the free Inpatient block of the hospital, where patients from a poor economical background are admitted and treated. There has been no documented complaint of any gastrointestinal complication such as diarrhoea, abdominal distension or constipation due to the intact polymeric formula, contrary to the published reports by various authors in their research carried out in different hospital settings. Hence, this present study was undertaken to prove the efficacy of this home based intact polymeric formula in the nutritional management and recovery of critically ill patients, while maintaining the safety standards.

AIM AND OBJECTIVES

This study was conducted with an aim to determine "The efficacy of a home based intact polymeric formula in the nutritional management and outcome of critically ill patients in a multispecialty tertiary care hospital", and its comparability with that of a standard commercial formula.

The objectives of the study were:

- To assess the nutritional status of critically ill patients requiring enteral nutrition support
- To plan and initiate enteral nutrition support in critically ill patients
- To determine the nutrient intake, timeliness of nutritional support and the factors interfering with the attainment of goals
- To assess the outcome of the patient by using the following parameters:
  - Gastrointestinal complications such as abdominal distension, constipation and diarrhoea
  - Length of stay in the ICU
  - Weaning off ventilation
  - Feed cost

METHODOLOGY

A prospective study was conducted on 30 subjects who were admitted to the Intensive Care Unit (ICU) in the Service Inpatient

Block and in the Medical Centre of Sri Ramachandra University (SRU). The study was conducted for a period of three months from January'09 till March '09.

The criteria which were followed for the selection of the study subjects were as follows:

Inclusion criteria

- Subjects who were admitted directly in the ICU
- Subjects who stayed in the ICU for > 3 days
- Subjects on Ryles Tube Feeding in the ICU for >7 days were included for analysis
- Subjects who were fed only standard commercial formulas

Exclusion criteria

- Subjects whose ICU stay was < 3 days
- Subjects who were on NPO for more than a week
- Subjects on disease specific enteral nutrition commercial formula
- Subjects on Ryles Tube Feeding in the ICU for <7 days were excluded from the analysis

STEPS

Nutritional assessment of critically ill patients requiring enteral nutrition support

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Estimating the requirement of the patients, initiation of feeds using intact polymeric formula and commercial formulas, transition and monitoring

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Documentation of the outcome variables in terms of the following

- Nutrient Intake
- Gastrointestinal complications
- Ventilation support days
- Length of stay
- Cost of overall nutritional management

RESULTS AND DISCUSSION

Subjects of both the genders were followed up during the study period. It was observed that there was an equal distribution of males and females in both the groups. Males constituted around 53.3% of the subjects and females around 46.7%. The mean ages of the males and females who were fed with the intact polymeric formula were 35.75±12.64 and 54.28±16.14 years, whereas the ages of those who were fed with the commercial formula were 44.50±18.92 and 42.28±21.31 years.

It was observed that a large percentage of subjects had neurological complications in both the groups (46.7% and 60.0% in the Intact Polymeric formula and the Commercial formula groups respectively), followed by orthopaedics and pulmonology related complications.

The mean heights of the subjects as determined by the summation of the body parts were 162.0±9.6 cm and 160.0±3.6 cm respectively. The average weights of the subjects in the two study groups were 62.4±9.41 kg and 64.8±10.7 kg respectively.

The recommended energy and protein intake for the subjects who were fed with the intact polymeric formula were 1799.33±379.62kcal and 63.53±18.33gm respectively and these values in those who were fed with the standard commercial formula were 1758.33±244.363 kcal and 62.33±6.87gm.

Nutrition support was initiated on the 3.00±1.55th day and on the 3.40±1.54th day of the ICU stay for the subjects who were being fed with the intact polymeric formula and the standard commercial formula respectively. Subjects receiving the intact polymeric formula were able to meet 100% of their requirements by 5.10±4.30 days and those receiving the standard commercial formula were able to do so by 2.86±0.91 days. Subjects receiving the intact polymeric formula were able to make a transition from enteral nutrition support to oral soft solids within 11.53±4.99 days and those receiving the standard commercial formula were able to do so within 9.46±3.18 days of the initiation of the enteral nutrition support.

Results of the efficacy of both the enteral support formulas on the outcomes of the subjects in this study, along with the feed costs, is presented below.

NUTRITIONAL SUPPORT DETAILS

Energy and Protein Intake

[Table/Fig 1] provides information on the nutrient intake of the subjects who received either of the formulas.

Parameters	IPF	CF	IPF	CF
	Initial		Final	
Energy(kcal) Mean± SD	788.09±748.95	849.07± 506.00	1522.47±630.49	1695.00±206.63
t- value	0.261 NS		1.007 NS	
Protein(gm) Mean± SD	28.27±31.19	36.89±32.58	54.20±27.46	85.12±62.12
t- value	0.74 NS		1.773 NS	
Percentage of Energy met	40.93±31.21	48.80±28.15	82.40±26.89	93.8 ±9.60
t- value	0.725 NS		1.546 NS	
Percentage of Protein met	41.13±31.14	52.13±30.77	82.27±24.65	95.27±8.78
t- value	0.973 NS		1.924 NS	

[Table/Fig 1]: Energy and Protein Intake

IPF: Intact polymeric formula; CF: Commercial formula

Advancement of the feeds was done, based on protocols [2]. On the day of initiation, the subjects who were fed with the intact polymeric formula received 788.09±748.95 kcal (40.93±31.21%) and 28.27±31.19 gm (41.13±31.1%) of protein, whereas the subjects who were fed with the standard commercial formula received 849.07± 506.00 kcal (48.80±28.15%) and 36.89±32.58gm (52.13±30.77%) of protein. The mean energy and protein intake of the two study groups on the day of initiation of the feeds did not show any significant difference.

During the build up phase of the feeding, there was an improvement in the percentage of energy and protein intake in the subjects who were fed with each formula. On the day of transition, the mean energy intake of the subjects who were fed with the intact polymeric formula was 1522.47±630.49kcal (82.40±26.89%) and 54.20±27.46gm (82.27±24.65%) of protein and that of the subjects who were fed with the standard commercial formula was 1695.00± 206.63 kcal (93.80±9.60%) and 85.12±61.72gm (95.27±8.78%) of protein respectively. There was no significant difference between the mean nutrient intakes of the two study groups on the day of transition from enteral to oral feeds, irrespective of the type of formulas which were used. It can be inferred from the above results, that intact polymeric formulas can also provide the same amount of energy and protein as the commercial formulas, if they are appropriately planned and reconstituted.

TIMELINESS OF NUTRITIONAL SUPPORT

The Timeliness of Nutritional Support includes three factors: the day of initiation of the feeds, the day of attainment of the goals and the day of transition [3]. In our study, the details regarding the timeliness of nutrition support by using either of the formula has been presented and discussed in [Table/Fig 2] under three factors.

Timeliness of Nutritional parameters	IPF (n=15)	CF (n=15)	t-value
Day of Initiation of feeds (d) Mean±SD	3.00±1.55	3.40±1.54	0.709NS
Day of attainment of goals (d) Mean±SD	5.10±4.30	2.86±0.91	1.767NS
Day of Transition (d) Mean±SD	11.53±4.99	9.46±3.18	1.354NS

[Table/Fig 2]: Timeliness of nutritional support

IPF: Intact polymeric formula; CF: Commercial formula

INITIATION OF THE FEEDS

Evidence based recommendations indicate that enteral nutrition can be initiated in adult patients within 24-72 hours after injury or acute illness, once the patient is resuscitated and stabilized in the intensive care setting [4]. As can be seen from [Table/Fig 2], enteral nutrition support was initiated by the 3.00 ±1.55th day and the 3.40±1.54th day of the ICU stay for the subjects who were being fed with the intact polymeric formula and the standard commercial formula respectively. No significant difference was found with respect to the day of initiation of the feeds between the two groups who were fed with the two different formulas.

ADVANCEMENT OF THE FEED RATE

Having started the enteral nutrition support, it is essential to advance the feed rate, to enable an early achievement of the goals. Gradual advancement of the feed rate by 15-30cc of feeds every 4-6 hours, would help in reducing the length of stay in the hospital. In this study, the advancement of the feed rate was done quarterly by 25ml to the target rate, as per the enteral nutrition support protocols. Subjects receiving the intact polymeric formula were able to meet 100% of their estimated requirements by 5.10±4.30 days and those receiving the standard commercial formula were able to do so by 2.86±0.91 days, inspite of some factors which impeded the nutrient intake. It is evident from the above results that both the type of formulas did not differ significantly with each other in attaining the target rate of feeding and in the attainment of the nutrient intake goals.

TRANSITION OF THE FEEDS

Management of the transition from enteral feeding to oral intake requires careful management. As soon as the patient is alert and is able to manage the mechanics of chewing and swallowing, the transition phase of enteral feeding may be started. When the voluntary intake approaches 50% of the nutrient requirements for more than two or three consecutive days, the enteral tube feedings can either be slowed, or the number of feedings can be progressively decreased [5].

Similar transition protocols were used in the study subjects and it was seen that the subjects who received the intact polymeric formula were able to make a transition from the enteral nutrition support to oral soft solids within 11.53±4.99 days and that those receiving the standard commercial formula were able to do so within 9.46±3.18 days of the initiation of the enteral nutrition support. No significant difference was observed while evaluating the time which was taken to make a transition from the enteral nutrition support to oral soft solids between the study groups who were fed with the two different formulas.

Hence, from the above discussion, it can be observed that there was no significant difference in the day of initiation of the feeds for the subjects in both the ICUs who were under study. The two different formulas which were used for the study did not differ significantly with respect to the day of attainment of the estimated nutrient goals and the day of transition from the enteral to the oral route. Therefore, the choice of formulas can either include an intact polymeric formula or a standard commercial formula for the nutritional support of critically ill patients. However, necessary steps should be followed for the careful reconstitution, administration, advancement and monitoring of nutrition support in order to obtain the necessary clinical outcome.

CLINICAL OUTCOMES OF NUTRITIONAL SUPPORT

Gastrointestinal Complications

Only one subject who received the intact polymeric formula out of the 15 subjects who were studied, reported to have three episodes of diarrhoea on only one day during the study period. However, the tube feeding rate was not slowed or halted altogether in this subject because of other possible contributing factors which were unrelated to the enteral formula or feeding such as medication, enteric pathogens, hypoalbuminaemia, and the underlying disease state.

LENGTH OF STAY

In our study, enteral nutrition support by using two formulas (the Intact polymeric formula or the Standard commercial formula) was initiated at the earliest i.e., within 72 hours of admission to the ICU.

[Table/Fig 3] shows that the average length of stay of the subjects who were being administered the intact polymeric formula was 17.2±6.5 days and that of those who were administered the standard commercial formula was 15.2±4.2 days.

Type of Formula	Length of stay in ICU (d) Mean ± SD	t- value
IPF (n=15)	17.2±6.5	0.987^{NS}
CF (n=15)	15.2±4.2	

[Table/Fig 3]: Length of stay

IPF: Intact polymeric formula; CF: Commercial formula

There was no significant difference between the two study groups in terms of their length of stay in the ICU, irrespective of the type of formula which was used and the severity of the illness. Patients who received the enteral nutrition support within the first 3 days of ICU admission had a significantly shorter stay in the ICU and if evidence based protocols were used in the nutritional management of the critically ill patients, the length of stay of the patients in the ICU could have been shortened, based on the severity of the disease.[6],[7]. Hence, it can be inferred that either of these two formulas can be used for critically ill patients who require enteral nutrition support, provided the nutrition support protocols are adhered to.

WEANING OFF VENTILATION

Mechanical ventilation is a method which can be used to mechanically assist or replace spontaneous breathing. Mechanical

ventilation is often a life-saving intervention, but it carries many potential complications including pneumothorax, airway injury, alveolar damage, and ventilator-associated pneumonia. Therefore, weaning off the ventilation at the earliest is necessary to prevent such complications. Studies have shown that early enteral nutrition helps in weaning off the patients from the ventilation faster [8].

In our study, enteral nutrition support by using both the two formulas was initiated at the earliest i.e., by the third day of admission to the ICU. The influence of the two types of formulas on the ventilator support days is presented in [Table/Fig 4]. It was seen that both the formulas had a similar effect on the ventilator support days. Subjects who were fed with the intact polymeric formula had taken 6.4±3.4 days to be weaned off the ventilator and the subjects who were fed with standard commercial formulas took 5.3±1.8 days for the same. However, no significant difference was found between the effects of the two formulas on the ventilator support days.

Type of Formula	Weaning of ventilation (d) Mean ± SD	t- value
IPF (n=15)	6.4±3.4	1.1074^{NS}
CF (n=15)	5.3±1.8	

[Table/Fig 4]: Weaning off Ventilation

IPF: Intact polymeric formula; CF: Commercial formula

FEED COSTS

In a tertiary care hospital which caters to the needs of patients from different economic backgrounds, selecting the appropriate method of nutrition support formula is necessary, in order for it to be cost effective, especially in developing countries. In our study, enteral nutrition support was being provided by using the intact polymeric formula and the standard commercial formula. The expenditure which was incurred in the usage of both the formulas is tabulated in the [Table/Fig 5]. Subjects who were fed with the intact polymeric formula, on an average, spent 363.2±293.7 rupees for nutrition support throughout their stay in the ICU. Subjects who were fed with commercial formulas spent 2967.0±1053.8 rupees when they are on enteral nutrition support.

It is generally believed that the overhead charges which are involved in the preparation of intact polymeric formulas are comparatively higher than that which are required for commercial formulas and moreover, the economic advantage of preparing intact polymeric formulas (based only on the cost of the ingredients) may be considerably offset by the increased medical costs resulting from their use.

Type of Formula	Feed cost (Rs) Mean ± SD	t- value
IPF (n=15)	363.2±293.7	9.218 *
CF (n=15)	2967.0±1053.8	

[Table/Fig 5]: Feed costs

IPF: Intact polymeric formula; CF: Commercial formula; *: significant at p< 0.05

In this study, all the overhead charges which were involved in the preparation of the intact polymeric formula were considered, such as the ingredient charges, fuel charges, electricity charges and labour charges. Having considered all these, it was found that the feed costs of the intact polymeric formula were much lower as compared to that of the standard commercial formulas and the results were statistically significant (p<0.05).

CONCLUSION

Therefore, in a multi specialty tertiary care hospital which caters to the nutritional needs of patients from different economic backgrounds, the choice of formulas should be made judiciously. If a standardized home based intact polymeric formula with appropriate techniques of reconstituting and administering is followed, the required goal can be achieved successfully without adding on to the economic burden of the poor patients.

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