Results & Discussion

RESULTS and DISCUSSION

Nutrition plays an important role in the complete care of the surgical patients. Surgical injury increases energy, protein demands. As a result of disease process and /or the operation itself, the nutritional status of a patient can quickly deteriorate due to diminished food intake, extensive nutrient losses and /or increased nutrient requirement. As a consequence, an increased risk exists for developing post-operative complications. Thus, patients recruited to such trial should be stratified as per the nutritional status and the type of surgical procedures. This would enable nutrition support to be more readily targeted to those surgical patients most likely to derive significant clinical benefit in terms of improved post-operative outcome. The rationale of providing anabolic (aminoacids) and energy (glucose) generating substrates either in the form of TPN or EN is to maintain or replenish lean body mass. Enteral nutrition always appears to be promising compared to TPN. Even a 'token' of it appears to have beneficial effect. Recent research focuses on quality rather than quantity nutrition and in this context immunonutrient glutamine has gained a lot of importance. Its supplementation may be associated with reduction in infectious complications and shorter hospital stay without adverse effect on mortality [*Novak et.al., 2002*] . With these considerations, the present work was planned to study the impact of substrate-enriched kitchen-based protein rich polymeric enteral diets with glutamine on the surgical gastrointestinal patients. In the present study patients enrolled have been stratified based on their nutritional status. Results are presented and discussed under the following sections.

SECTION I:

In this section, the observation of the survey conducted in the ICUs' of selected hospitals of Ahmedabad, Gujarat is presented in order to understand the general disease prevalence pattern and more specifically to identify the gastrointestinal disease profile of the hospitalised patients. The data obtained represents baseline information.

SECTION II:

This section presents the data on impact of routine hospital diet (*EnR*) and two kitchen-based polymeric protein rich enteral diets with sources of protein from soy (*EnS*) and milk (*EnM*) in subjects undergoing surgical gastrointestinal procedures. Comparison and the effect of diets are studied on overall improvement in nutritional status. Additionally, influence in overall weight gain/loss, length of stay and cost effectiveness has also been discussed here.

SECTION II:

Results between impact of *substrate enrichment* of routine hospital enteral diet (*GEnR*) and two kitchen-based polymeric protein rich enteral diets with sources of protein from soy (*GEnS*) and milk (*GEnM*) along with glutamine in subjects undergoing surgical gastrointestinal procedures are presented. Impact of diets on overall improvement in nutritional status as per the previous section has been assessed here.

SECTION I

Situational Analysis of Positional Status Of Gastrointestinal Diseases In the ICU's of Selected Hospitals of Ahmedabad

Smooth functioning of the intricately related secretory and neuromuscular mechanisms of the gastrointestinal (G.I) system reflects the physical and psychological conditioning of the body. Various G.I. diseases and organ dysfunctions at any point of time disrupt normal operation of the mechanisms. Diseases of acute nature and surgical procedures call for the patients' hospitalisation in the intensive care units (ICU) for proper medical interventions [*Williams and Anderson 1996*]. Chronic G.I problems result in malnutrition and increased morbidity and mortality. Therefore, it was intended to ascertain the positional status of the G.I. diseases of ICU patients compared to other major diseases. The present investigation was aimed at understanding the types of gastrointestinal patients admitted to the ICU's of a few selected hospitals of Ahmedabad based on retrospective records For the ethical reasons, the names of the hospitals are not disclosed but are represented as A, B and C. The observation covered represents the case records of ICU patients only. This would help the hospital concerned to be in a readiness for handling the G.I. patients more promptly and efficiently.

OBSERVATIONS:

1. **Patients' General Profile:**

Table 1 represents the data of the distribution of patients in the three hospitals. There were 143, 305 and 554 totaling 1002 patients. The hospital C, therefore, admitted more than half of the total patients, followed by the hospital B and A [Table 1] [Fig 7]. In general the distribution of patients on gender (females : males) is about 1:2 in all three hospitals.

2. **Disease Distribution Profile:**

Case records indicated that the patients admitted in the ICU of the three hospitals had a range of complications of which 47.6 % had cardiac associated diseases and 20.4 % had only gastrointestinal problems. Rest 31.9 % had other types of complications [Table 2] [Fig 8]. In overall analysis, males were found to be more than females in all categories of patients.

3.Gastrointestinal Disease Profile:

There were 204 patients admitted to the ICUs with different types of gastrointestinal problems of which abdominal hernia (14), appendicitis (19), Calculus cholecystitis (33), hemorrhoids (11), intestinal obstruction (13), and exploratory laparotomy (15) formed the major components totaling 105 (51.4 %) patients. The rest 48.5 % patients had other types of G.I problems such as sigmoid-colectomy, spleenectomy, bleeding of duodenal ulcer, illeostomy closure, abdominal injury, pancreatitis, internal piles and hepatic encepalopathy etc. Hospital A (63.7 %) had more number of G.I cases, B had 23.0 % and C had 13.2 % [Table 3] [Fig 9].

4. Length of ICU Stay of Survived And Expired Patients:

Length of the ICU stay varied from couple of days to a maximum of 28 days. Among 1002 cases, admitted in the ICU, the survival rate was found to be 96.6 %. The length of the ICU stay was found to be 1-7 days in 817 cases, 8 -14 days in 109 cases and above 15 days in 42 cases. A total of 34 (3.4%) patients out of 1002 expired. The mortality rates were 2.1 %, 1.6 % and 4.7 % in hospitals A, B and C, respectively. Numbers of deaths due to gastrointestinal diseases were found to be 2 and 3 in hospitals A and C, respectively. Most of the patients expired were from those who had a very short stay in ICU (1 - 7 days) [Table 4].

Table1: PATIENTS PROFILE: NUMBER, GENDER AND AGE OF THE ICU PATIENTS

	HOSPITALS						TOTAL
	A		B		C		
	M	F	M	F	M	F	
Number of patients	97	46	205	100	382	172	1002
Mean Age	45.81	48.54	50.43	41.12	56.37	58.29	
SD	17.91	17.76	19.45	19.64	15.59	17.11	
M (male) F (female)							

Table 2: DISEASE DISTRIBUTION AND GENDER DOMINANCE PATTERN THE ICU'S OF THE HOSPITALS

SINGLE / MULTIPLE COMPLICATIONS	HOSPITALS			TOTAL
	A	B	C	
Cardiac Disease	-	34 (26 + 8)	333 (240 + 93)	367 (36.62 %)
Cardiac Associated Diseases	7 (1 + 6)	20 (13 + 7)	83 (50 + 33)	110 (36.62 %)
Gastrointestinal Disease	130 (93 + 37)	47 (30 + 17)	27 (18 + 9)	204 (20.35 %)
Gastro associated Diseases	1 (1 + 0)			1 (0.09 %)
Neurology Disease	1 (1 + 0)	89 (59 + 30)	31 (20 + 11)	121 (12.07 %)
Pulmonary Disease	-	31 (19 +12)	31 (24 + 7)	62 (12.07 %)
Others	4 (2 + 2)	84 (58 + 26)	49 (30 + 19)	137 (13.67 %)
TOTAL	143 (97 + 46)	305 (205 + 100)	554 (382 + 172)	1002

Table 3: DISEASE DISTRIBUTION AND GENDER DOMINANCE PATTERN OF G.I DISEASES

DISEASES	HOSPITALS (Male +Female)			TOTAL
	A	B	C	
Abdominal hernia	14 (10 + 4)	(-)	(-)	14 (6.8 %)
Appendicitis	19 (15 + 4)	(-)	(-)	19 (9.3 %)
Bleeding duodenal ulcer	2 (2 + 0)	6 (3 + 3)	(-)	8 (3.9 %)
Calculus cholecystitis	29 (17 +12)	3 (2 + 1)	1 (0 + 1)	33 (16.1 %)
Cirrhosis	(-)	(-)	2 (2 + 0)	2 (0.9 %)
Colostomy	(-)	(-)	3 (2 + 1)	3 (1.5 %)
Hemorrhoids	6 (5 + 1)	4 (2 + 2)	1 (1 + 0)	11 (5.3 %)
Hepatic encephalopathy	(-)	2 (2 + 0)	2 (2 + 0)	4 (2 %)
Hepatitis	(-)	(-)	2 (2 + 0)	2 (1 %)
Intestinal obstruction	10 (6 + 4)	3 (2 + 1)	(-)	13 (6.3 %)
Laparotomy	3 (2 +1)	5 (2 + 3)	7 (4 + 3)	15 (7.3 %)
Pancreatitis	(-)	4 (3 + 1)	2 (0 + 2)	6 (2.9 %)
Perforation	(-)	(-)	2 (1 + 1)	2 (1.0 %)
Spleenectomy	5 (3 +2)	1(0 + 1)	(-)	6 (2.9 %)
Others	42 (33 + 9)	19 (14 + 5)	5 (4 + 1)	66 (32.3 %)
TOTAL	130 (63.7%)	47 (23.0%)	27 (13.2%)	204

Table 4: NUMBER OF SURVIVED AND EXPIRED ICU PATIENTS IN THE HOSPITALS

LENGTH OF HOSPITAL STAY	HOSPITALS			TOTAL
Survived Patients (Days)	A	B	C	
1 - 7	91	226	500	817
8 - 14	26	56	27	109
> 15	23	18	1	42
TOTAL	140	300	528	968
Expired Patients (Days)	(Male + Female)			
1 - 7	2 (1 + 1)	4 (3 + 1)	26 (18 + 8)	32 (22 + 10)
8 - 14	1 (1 + 0)	1 (0 + 1)	0	2 (1 + 1)
TOTAL	3 (2 + 1) (2 *)	5 (3 + 2) (-)	26 (18 + 8) (3 *)	34 (23 + 11) (5*)
*Number of Expired patients due to Gastrointestinal diseases				

Fig 7: Disease Distribution Pattern in Hospitals of Ahmedabad (n = 1002)

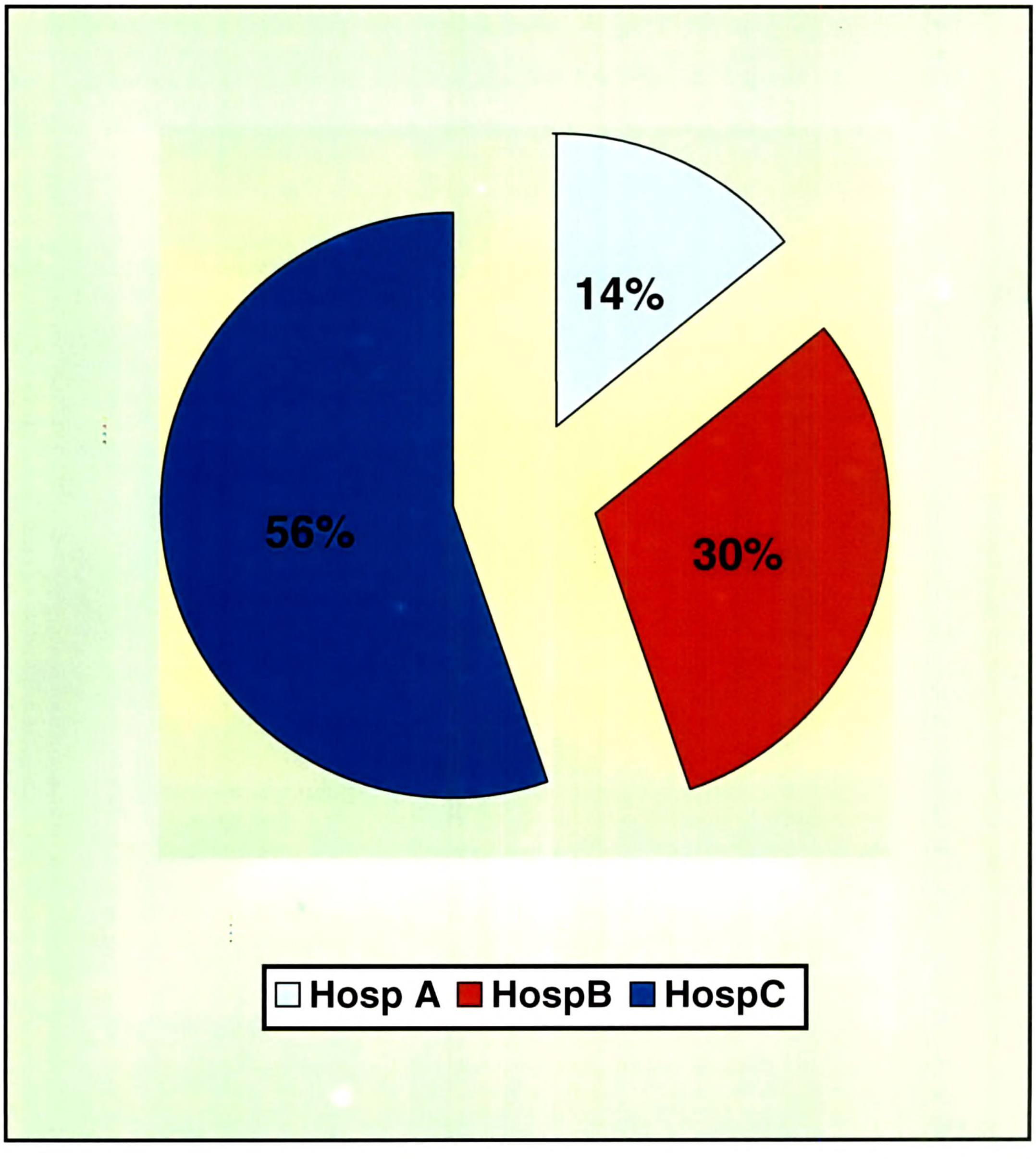


Fig 8: Disease Distribution Pattern of (ICU) Selected Hospitals of Ahmedabad (n=1002)

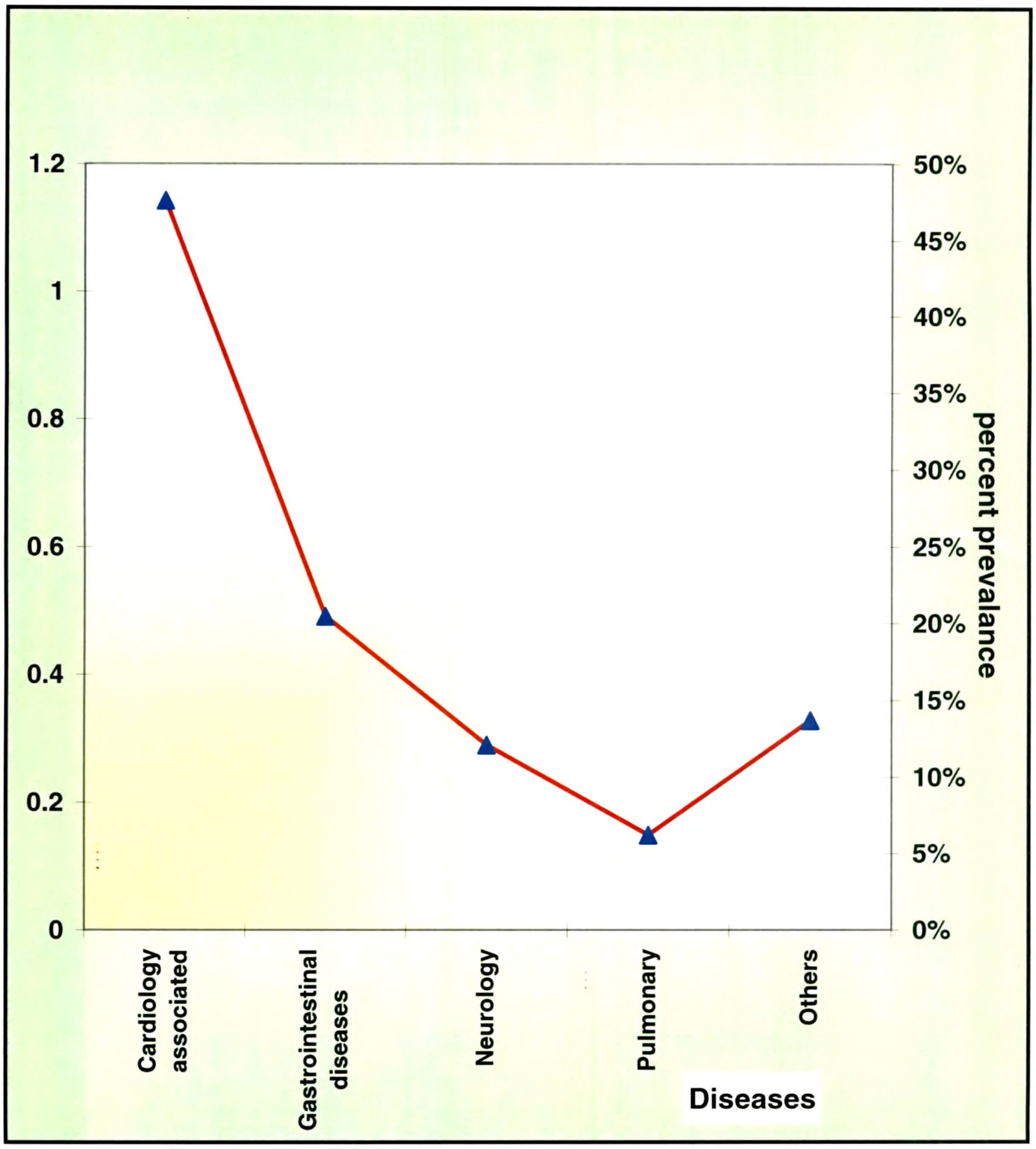
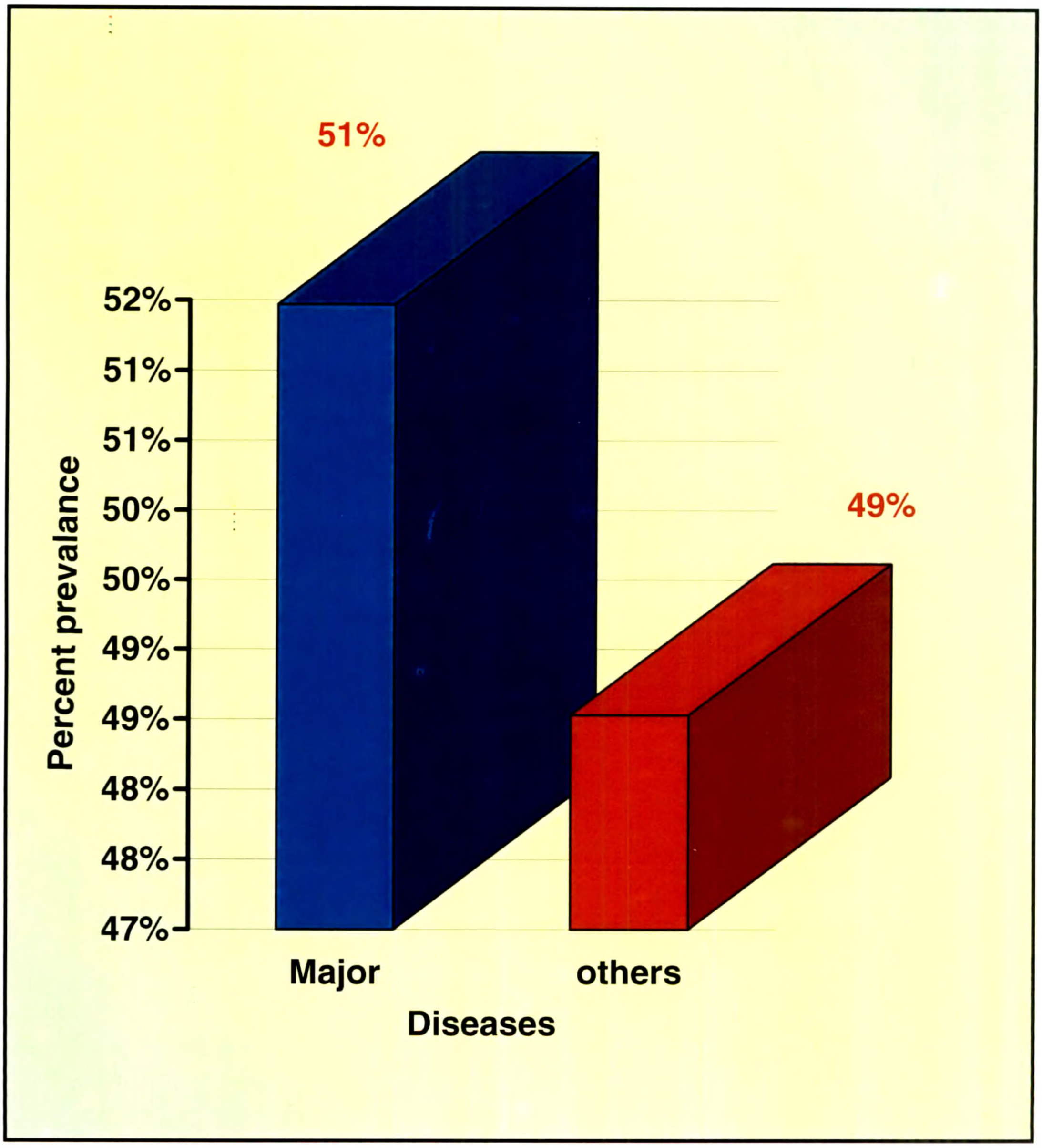


Fig 9: Gastrointestinal Disease Distribution Profile



SECTION II

Routine Hospital Enteral diet (*EnR*) *Vs* Kitchen-based Polymeric Protein rich Enteral diets (*EnS and EnM*)

In this section, the patients were given kitchen based polymeric enteral diets with sources of protein either *soy* (*EnS*, group 2) or *milk* (*EnM*, group 3) and control group (*EnR*, group 1) was given *routine hospital* enteral diet. The enteral diets were delivered through transnasal or enterostomy tubes during post - operative enteral stage to the surgical gastrointestinal (G.I) patients as per predetermined protocol.

RESULTS:

1.DEMOGRAPHIC PROFILE:

Demographic profile of the hospitalised subjects is presented in Table 5.
The mean age of the subjects (n = 61) in the three groups *EnR*, *EnS*, *EnM* were 39.9 years (*range*: 20 - 60 years), 43.3 years (*range*: 17 - 65 years) and 37.9 years (*range*: 17 - 65 years), respectively. In the present study, there were 14 types of gastrointestinal diseases (G.I) observed in the patients. *EnR* study group had 12 types, *EnS* study group had 9 types and *EnM* had 13 types of diseases. Of these 67.2 % were of upper G.I diseases, 13.1 % were of lower G.I diseases and 19.7 % were of miscellaneous types.

2.NUTRITIONAL ASSESSMENT:

(i) Anthropometric Profile:

The anthropometric assessment and nutritional risk index rating of the study groups were done soon after hospitalisation and the data is represented in Table 6.

a. Height and Weight: The average height and weight of the subjects on admission ranged from 146.0 -180.0 cm (mean: 160.0 cm) and 24.0 - 91.0 Kg (mean: 53.5 Kg).

b. Weight Loss on Admission: More than 10 % of weight loss as compared to usual body weight (UBW) was noticed in 57.0 % of the subjects on admission, whereas loss of less than 10 % of UBW was noticed in 15.0% of the subjects.

c. Body Mass Index (BMI): There were three categories of patients in the study group as underweight, normal, overweight based on BMI classification. The *'underweight'* [*BMI ≤ 18.5*] category patients were 28.6 % (*EnR*), 40.0 % (*EnS*) and 35.0 % (*EnM*) patients; *'normal'* [*BMI: 18.5 - 24.9*] category patients were 33.3 % (*EnR*), 45.0 % (*EnS*) and 50.0% (*EnM*) whereas, 38.1 % (*EnR*), 15.0% (*EnS*) and 10.0 % (*EnM*) were in *'overweight'* [*BMI: 24.9 - 29.9*] category.

(ii) Nutritional Risk Index (NRI):

Nutritional Risk Index (NRI) was calculated as per the formula highlighted in the materials and methods (p. 94). The mean values for the three groups were 2.77 gdl^{-1}, 3.07 gdl^{-1} and 2.97 gdl^{-1} and were found to be lower as compared to their normal levels (Alb: 3.8 - 5.0 gdl^{-1}). The NRI score rated 61.9 % (*EnR*), 60.0 % (*EnS*) and 55.0 % (*EnM*) as severely malnourished (*Sm*) subcategory. Mild-moderately malnourished (*Mm*) subcategory comprised of 19.0 %, 25.0 %, 25.0 % and well nourished (*Wn*) subcategory comprised of 19.0 %, 15.0 % and 20.0 % for the respective, *EnR*, *EnS*, *EnM* study group [Fig 10]. Thus, an average of 58.9 % were rated as 'Sm' subcategory among the three study groups. Based on NRI score, these subcategories were taken into consideration for interpretation of results.

3. NUTRIENT INTAKE:

The patients were on their own diet during pre-operative stage. In the post-operative stage [total parenteral nutrition (TPN) and enteral nutrition (EN)] based on surgical procedure needed, patients were kept on TPN followed by EN or directly on EN.

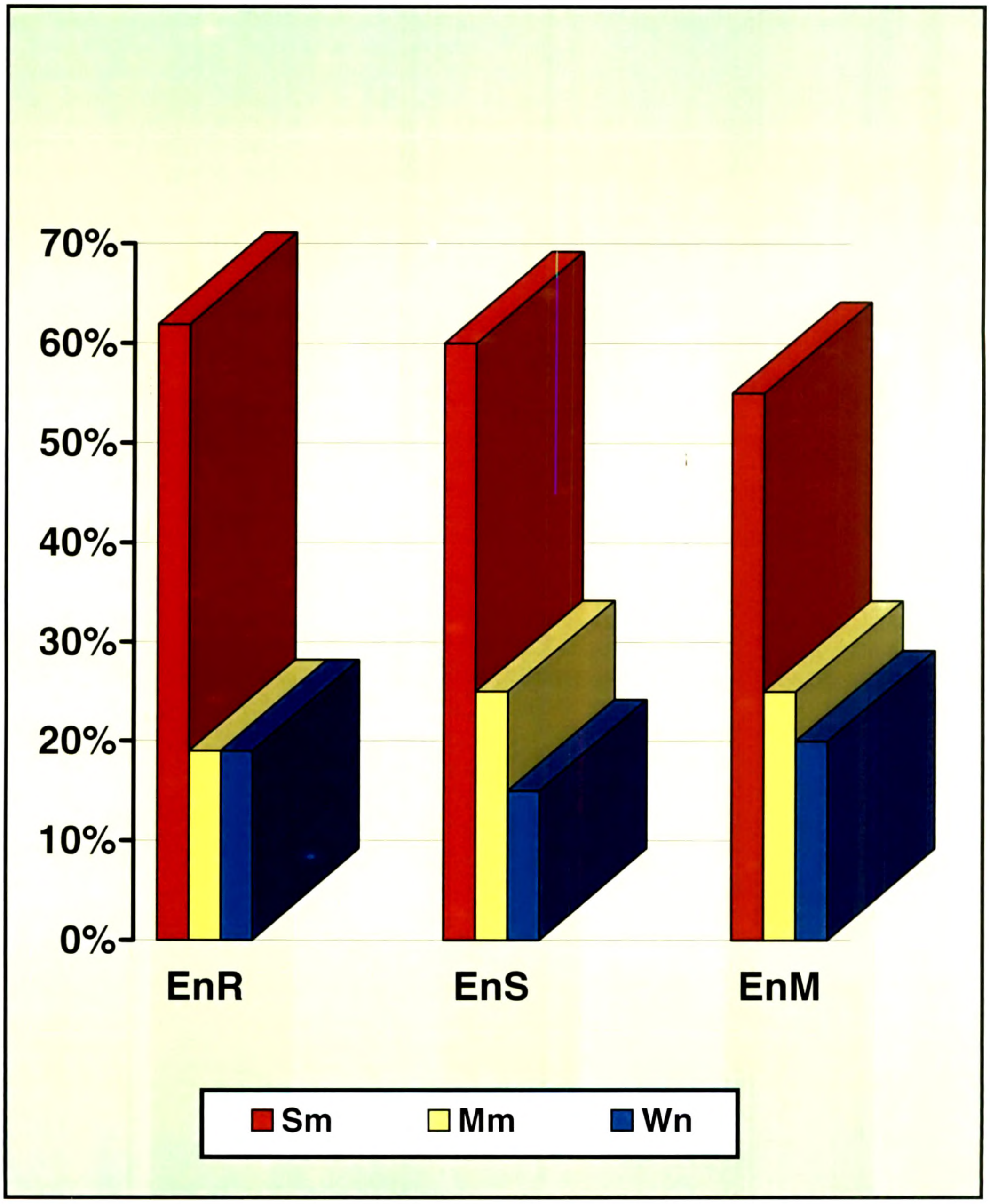
Table 5: Demographic Profile (n = 61)

	Particulars	Groups		
		EnR	*EnS*	*EnM*
I.	Subjects (Male + Female)	21(16M + 5F)	20(15M + 5F)	20 (14M + 6F)
II.	Mean Age (years)	39.9	43.3	37.9
III.	Diagnosis:			
	Upper G.I Diseases (67.2 %)			
	Oesophageal stricture	1	4	2
	Ca-oesophagus	0	2	5
	Duodenal perforation	1	1	2
	Acute pancreatitis	4	3	2
	Chronic pancreatitis	1	1	1
	Pancreatic trauma	1	2	1
	Adenocarcinoma of pancreas	1	5	1
	Lower G.I Diseases (13.1 %)			
	Ca-colon	1	1	1
	Fecal fistula	4	0	1
	Miscellaneous (19.7 %)			
	Ulcerative colitis	4	0	0
	Perforated appendicitis	1	0	1
	Intestinal obstruction	1	0	1
	Hepatic necrosis	1	0	1
	CBD-obstruction	0	1	1

Table 6: Nutritional Status On Admission (n = 61)

	Particulars	Groups		
		EnR (n=21)	*EnS* (n=20)	*EnM* (n=20)
I	Height (cm) (range:146 - 180 cm)	162.0 ±10.5	160.2 ± 7.5	159.7±10.1
II	Weight (Kg) (range: 24 - 91 Kg)	58.2 ± 12.8	51.2 ± 15.0	51.3±14.4
III	Loss of weight:			
	<10% of UBW (mean loss:15.0 %)	2 (9.5 %)	4 (20.0 %)	3 (15.0 %)
	>10% of UBW (mean loss: 57.0 %)	11 (52.4 %)	11 (55.0 %)	13 (65.0 %)
IV	*Body Mass Index* (BMI):			
	18.5 or below (Underweight category)	6 (28.6 %)	8 (40.0 %)	7 (35.0 %)
	18.5-24.9 (Normal category)	7 (33.3 %)	9 (45.0 %)	10 (50.0 %)
	24.9-29.9 (Overweight category)	8 (38.1 %)	3 (15.0 %)	2 (10.0 %)
V	*Mean Serum Albumin* (gdl^{-1}):	2.77 #	3.00 #	2.97 #
VI.	*Nutritional Risk Index* (NRI):			
	Severely malnourished (Sm)	13 (61.9 %)	12 (60.0 %)	11 (55.0 %)
	Mild-moderately malnourished (Mm)	4 (19.0 %)	5 (25.0 %)	5 (25.0 %)
	Well nourished (Wn)	4 (19.0 %)	3 (15.0 %)	4 (20.0 %)
#Albumin level at nutritional risk (normal levels: 3.8-5.0 gdl^{-1})				

Fig 10: Nutritional Risk Index
(n = 61)



Supplementation of feeding formulas was done during post-operative enteral nutrition stage.

The diet intake (pre-operative stage and post-operative EN stage) along with their requirements for the study groups are presented in Table 7 and 8 (a, b, c).

(i) Pre-operative Nutrient Intake by the Study Groups:

Pre-operative nutrient intake in general for the study groups (*EnR*, *EnS, EnM*) were less compared to their requirements. The average energy (1,024.5 Kcal), carbohydrate (124.5 g), protein (48.2 g) and fat (35.3 g) intakes were significantly lower in *EnR* study group than their requirement ($p < 0.05$). Similarly, the energy and protein intakes were found to be significantly lower than their requirements in *EnS* study group (energy: 1,787.7 Kcal, carbohydrate: 272.4 g, protein: 45.9 g, fat: 61.3 g). In case of *EnM* group all the macronutrient levels were significantly lower ($p<0.05$) as compared to their requirements (energy: 1,530.4 Kcal, carbohydrate: 222.7 g, protein: 37.4 g, fat: 43.6 g) [Table 7].

Nutrient intake by the subjects in the subcategories based on NRI Score:

a. *EnR* Study group:

All the subcategories *viz.,* Sm, Mm, Wn had significantly lower intakes with respect to carbohydrate, protein and fat resulting in low energy intake. The mean values of each subcategory were energy: 1,144.0 Kcal, carbohydrate: 159.1 g, protein: 51.6 g, fat: 41.2 g in Sm subcategory; energy: 483.3 Kcal, carbohydrate: 68.4 g, protein: 14.62g, fat: 11.8 g in Mm subcategory and energy: 1,175.5 Kcal, carbohydrate: 68.0 g, protein: 57.0 g, fat: 34.0 g in Wn subcategory [Table 8 (a, b, c)].

b. *EnS* Study group:

In case of *EnS* study group, Sm (energy: 1,656.0 Kcal, carbohydrate: 266.2 g, protein: 41.3 g, fat: 50.0 g), Mm (energy: 1,940.1 Kcal, carbohydrate: 278.8 g, protein: 49.4 g, fat: 76.2 g) and Wn (energy: 2,155.0 Kcal, carbohydrate: 291.4 g, protein: 61.5 g, fat: 90.3 g), thus showing insufficient intake of protein in Sm subcategory ($p < 0.05$) as compared to their requirement [Table 8 (a, b, c)].

c. *EnM* Study group:

The nutrient intakes recorded were: Sm - energy: 1,456.3 Kcal, carbohydrate: 219.6 g, protein: 32.7 g, fat: 44.6 g, Mm - energy: 1,444.4 Kcal, carbohydrate: 195.1 g, protein: 38.8 g, fat: 33.3 g, Wn - energy: 1,823.3 Kcal, carbohydrate: 265.5 g, protein: 48.3 g, fat: 53.6 g, thus showing a significant low intake of protein in all subcategories. The energy was found to be lower in Sm subcategory than the required amount [Table 8 (a, b, c)].

(ii) Post-operative Nutrient Intake by the Study Groups:

The data on post-operative diet intake is presented in the Table 7.

During post-operative EN stage, nutrient intake was significantly lower in *EnR* study group (energy: 1,361.4 Kcal, carbohydrate: 154.3 g, protein: 39.7 g, fat: 43.5g) as compared to their requirements. The calories, carbohydrate, protein and fat intake by *EnR* study group was significantly ($p < 0.05$) lower as compared to their requirements. A better intake was noted in *EnS* study group (energy: 1,873.3 Kcal, carbohydrate: 273.4 g, protein: 100.3 g, fat: 64.0 g) and *EnM* study group (energy: 1,817.2 Kcal, carbohydrate: 272.2 g, protein: 91.9 g, fat: 55.6 g) as compared to their requirement. The protein intake was noted significantly low in *EnM* study group compared to their requirement ($p < 0.05$).

The data from the table also indicate that the energy intake (1361.4 Kcal *vs* 1024.5 Kcal) in *EnR*, (1873.3 Kcal *vs* 1787.7 Kcal) in *EnS* and (1817.2 Kcal *vs* 1530.4 Kcal) and in *EnM* study group was much better in the post-operative EN stage as compared to the pre-operative stage. Similar observation was found with respect to carbohydrate and protein in all the study groups. In *EnS* and *EnM* study groups, protein intake was found to be significantly higher in post-operative EN stage as compared to pre-operative stage ($p < 0.05$).

Nutrient Intake by the Subjects in the Subcategories based on NRI Score:

a. *EnR* Study group:

The subcategories of *EnR* study group recorded considerably low intake of major nutrients thereby resulting in lower energy as compared to their requirements. All the three subcategories, Sm, Mm, Wn had significantly lower intake of energy and protein [Sm (energy: 1,361.4 Kcal, carbohydrate: 154.3 g, protein: 39.7 g, fat: 43.5 g), Mm (energy: 1,325.0 Kcal, carbohydrate: 166.0 g, protein: 38.9 g, fat: 41.0 g) and Wn (energy: 1,296.0 Kcal, carbohydrate: 166.0 g, protein: 37.5 g, fat: 50.0 g)]. In all the three subcategories the values were found to be significantly lower as compared to their requirement [Table 8 (a, b, c)].

b. *EnS* Study group:

The subcategories of *EnS* study group recorded better intakes of major nutrients thereby resulting adequate intake of energy as compared to their requirements. The energy and protein intakes were adequate for Sm (energy: 1,929.4 Kcal, carbohydrate: 284.1 g protein: 106.1 g, fat: 66.9 g) and Mm (energy: 1,883.1 Kcal, carbohydrate: 266.5 g, protein: 92.5 g, fat: 58.8 g) subcategories. Protein intake was found to be significantly high for both the groups. Wn subcategory had (energy: 1,617.5 Kcal, carbohydrate: 236.6 g, protein: 86.1 g, fat: 58.0 g) significantly lower energy ($p < 0.05$) whereas, protein intake was adequate as compared to their requirement [Table 8 (a, b, c)].

c. *EnM* Study group:

The Sm subcategory of *EnM* study group had significantly lower intake of energy and protein ($p < 0.05$) as compared to their requirements (energy: 1,800.0 Kcal, carbohydrate: 270.1 g, protein: 94.9 g, fat: 52.6 g). The energy and protein intakes of Mm (energy: 1,773.2 Kcal, carbohydrate: 266.4 g, protein: 82.1 g, fat: 54.4 g) and Wn (energy: 1,919.3 Kcal, carbohydrate: 285.3 g, protein: 95.8 g, fat: 65.3 g) were found to be adequate as compared to their requirement [Table 4 (a, b, c)]. In all the three subcategories protein intakes were found to be significantly low compared to their requirement ($p < 0.05$) [Table 8 (a, b, c)].

In general the important macronutrient that is protein intake was significantly higher in Sm, Mm subcategories belonging to *EnS* study group. Even though the levels recorded were not statistically significant, there was improvement in protein intake by Wn subcategory. In case of *EnM* study group protein was significantly higher in all

Table 7: Assessment of Nutrient Intake: *Average Requirements Vs Average Intakes* (n = 61)

Study Groups	Energy (Kcal)	Carbohydrate (g)	Protein (g)	Fat (g)
	REQUIREMENT			
EnR (n = 21)	2147.1 ±202.9	320.8 ±30.0	96.8 ±9.8	69.9 ±8.1
EnS (n = 20)	1930.8 ±187.7	281.5 ±28.9	101.5 ± 9.4	62.9 ±4.8
EnM (n = 20)	1953.9 ±255.2	286.9 ±25.0	102.0 ±13.4	60.4 ±14.9
AVERAGE INTAKE				
Pre-operative Stage				
EnR (n = 21)	1024.5 * ±563.2	124.5 * ±90.6	48.2 * ±28.1	35.3 * ±23.5
EnS (n = 20)	1787.7 * ±654.2	272.4 ±123.2	45.9 * ±19.2	61.3 ±43.2
EnM (n = 20)	1530.4 * ±452.9	222.7 * ±81.6	37.4 * ±13.4	43.6 * ±25.3
Post-operative EN Stage				
EnR (n = 21)	1361.4 * ±393.8	154.3 * ±61.7	39.7 * ±19.2	43.5 * ±17.6
EnS (n = 20)	1873.3 @ ±239.5	273.4 ±33.0	100.3 #@ ±22.4	64.0 ±19.0
EnM (n = 20)	1817.2 #@ ±271.0	272.2 ±41.6	91.9 * #@ ±17.3	55.6 ±23.3

* Significantly lower intake than the required intake $p < 0.05$
# Significantly higher intake than the pre-operative stage $p < 0.05$
@ Significantly higher intake as compared to control group (EnR) ($p < 0.05$)

Table 8 (a): Assessment of Nutrient Intake: *Average Requirements Vs Average Intakes of 'Severely Malnourished' Subcategory (Sm) as per NRI Score*

Study Groups	Energy (Kcal)	Carbohydrate (g)	Protein (g)	Fat (g)
	REQUIREMENT			
EnR (n = 13)	2140.0 ±209.9	320.8 ±31.4	97.2 ±10.7	69.0 ± 9.1
EnS (n = 12)	1948.8 ±161.9	285.1 ±26.2	102.2 ±7.9	64.0 ±12.9
EnM (n = 11)	2033.8 ±303.8	299.4 ±43.9	105.3 ±15.9	65.5 ±14.9
AVERAGE INTAKE				
	Pre-operative Stage			
EnR (n = 13)	1144.0 * ±572.4	159.1 * ±93.9	51.6 * ±19.3	41.1 * ±26.3
EnS (n = 12)	1656.0 ±650.2	266.2 ±153.2	41.3 * ±15.3	50.0 ±34.9
EnM (n = 11)	1456.3 * ±545.5	219.6 ±83.7	32.7 * ±13.2	44.6 ±30.4
	Post-operative EN Stage			
EnR (n = 13)	1326.5 ** ± 424.9	146.7 ±69.5	40.7 ** ±22.1	42.7 ±18.3
EnS (n = 12)	1929.4 ±244.9	284.1 ±32.0	106.1 #@ ±22.3	66.9 ±21.2
EnM (n = 11)	1800.0 * ±310.7	270.1 ±51.1	94.9 * #@ ±17.1	52.6 ±26.0

* Significantly lower intake than the required intake $p < 0.05$
** Significantly lower intake than the required intake $p < 0.01$
# Significantly higher intake than the pre-operative stage $p < 0.05$
@ Significantly higher intake in Sm subcategory of EnS and EnM study groups than the Sm subcategory of EnR study group $p < 0.05$.

Table 8 (b): Assessment of Nutrient Intake: *Average Requirements Vs Average Intakes of 'Mild-Moderately Malnourished' Subcategory (Mm) as per NRI score*

Study Groups	Energy (Kcal)	Carbohydrate (g)	Protein (g)	Fat (g)
	REQUIREMENT			
EnR (n = 4)	2194.0 ±268.0	323.0 ±38.8	96.9 ±11.6	71.7 ±8.6
EnS (n = 5)	1895.5 ±307.0	274.7 ±44.5	99.5 ±16.1	61.1 ±21.9
EnM (n = 5)	1800.0 ±187.1	257.4 ±29.9	94.6 ±9.9	54.4 ±15.7
AVERAGE INTAKE				
	Pre-operative Stage			
EnR (n = 4)	483.3 * *(range: 170- 1276)*	68.4 * ±51.7	14.6 * ±7.6	11.8 * ±4.6
EnS (n = 5)	1940.1 ±747.2	278.8 ±32.2	49.4 ±24.2	76.2 ±56.0
EnM (n = 5)	1444.4 ±316.0	195.1 ±96.5	38.8 * ±12.8	33.3 ±10.2
	Post-operative EN			
EnR (n = 4)	1325.0 * ±469.0	166.0 ±31.6	38.9 * ±20.8	41.0 ±11.0
EnS (n = 5)	1883.1 ± 70.4	266.5 ±18.1	92.5 # ±2.3	58.8 ±17.2
EnM (n = 5)	1773.2 ±243.3	266.4 ±30.5	82.1 * # ±16.6	54.4 ±19.6

* Significantly lower intake than the required intake $p < 0.05$
** Significantly lower intake than the required intake $p < 0.01$
# Significantly higher intake than the pre-operative stage $p < 0.05$

Table 8 (c): ***Assessment of Nutrient Intake:*** *Average Requirements Vs Average Intakes of 'Well - Nourished' (Wn) Subcategory as per NRI Score*

Study Groups	Energy (Kcal)	Carbohydrate (g)	Protein (g)	Fat (g)
REQUIREMENT				
EnR (n = 4)	2125.0 ±150.0	318.8 ±22.5	95.6 ±6.8	70.8 ±5.0
EnS (n = 3)	1900.0 ±173.2	275.5 ±25.2	101.3 ±8.1	60.4 ±18.7
EnM (n = 4)	1946.7 ±85.9	282.3 ±12.4	102.2 ±5.5	53.8 ±11.0
AVERAGE INTAKE				
	Pre-operative Stage			
EnR (n = 4)	1175.5 * ±193.6	68.0 * ±56.6	57.0 ±44.0	34.0 * ±16.0
EnS (n = 3)	2155.0 ±574.8	291.4 ±24.2	61.5 ±26.6	90.3 ±56.2
EnM (n = 4)	1823.3 ±244.4	265.5 ±51.2	48.3 * ±9.7	53.6 ±22.4
	Post-operative EN			
EnR (n = 4)	1296.0 * ±296.1	166.0 ±69.2	37.5 * ±7.5	50.0 ±23.0
EnS (n = 3)	1617.5 * ±242.4	236.6 ±29.6	86.1 ±16.6	58.0 ±12.1
EnM (n = 4)	1919.3 ±214.7	285.3 ±27.1	95.8 * # ±18.3	65.3 ±22.7

* Significantly lower intake than the required intake $p < 0.05$
** Significantly lower intake than the required intake $p < 0.01$
\# Significantly higher intake than the pre-operative stage $p < 0.05$

the subgroups in the post-operative stage as compared to pre-operative stage ($p < 0.05$). Such an observation was not observed in control group (*EnR*).

Comparison in adequacies of post-operative intake among groups further reflected that energy and protein intakes were significantly higher in *EnS* and *EnM* study groups compared to *EnR* study group ($p < 0.05$)[Mann Whitney U-test or Wilcoxon test] [Table 7]. Further, protein intake in Sm subcategory was found to be significantly higher in *EnS* and EnM study group compared to Sm subcategory of *EnR* study group [Table 8(a)].

4. FEEDING RELATED COMPLICATIONS:

Feeding related complications were more for *EnR* study group (tube occlusion, abdominal distension, diarrhoea etc.). *EnM* study group had complaints of abdominal distension and diarrhoea but with lesser frequency whereas, *EnS* study group had very few complaints of abdominal distension only.

Feed related complications in *EnR* study group was observed more in Sm subcategory followed by Mm and Wn subgroups. In EN stage, these complications were predominantly related to symptoms of gastrointestinal intolerances (aspirates, vomiting, abdominal bloating and diarrhoea).

5. OUTCOME MEASURES:

Impact of Diets on Biochemical Parameters in the study groups:

The biochemical profile (before and after supplementation of diets) of the patients from different study groups is presented in Table 9 (a).

In the post-operative stage, hemoglobin levels did not alter much in all the three study groups (*EnR*: 9.74 gdl^{-1} *vs* 10.48 gdl^{-1}; *EnS*: 11.20 gdl^{-1} *vs* 11.37 gdl^{-1}; *EnM*: 10.56 gdl^{-1} *vs* 10.07 gdl^{-1}). In case of total protein, both *EnS* and *EnM* groups showed an improvement after post-operative EN stage compared to pre-operative stage (*EnS*: 6.60 gdl^{-1} *vs* 6.18 gdl^{-1}; EnM: 6.00 gdl^{-1} *vs* 5.82 gdl^{-1}). *EnR* study group showed a negligible drop in the total protein (4.84 gdl^{-1} *vs* 4.99 gdl^{-1}) in the post-operative stage. Similarly, both *EnS* and *EnM* showed an improvement in albumin level after post-operative EN stage as compared to pre-operative stage (*EnS:* 3.44 *vs.* 3.10 gdl^{-1}; *EnM*: 3.1.0 gdl^{-1} *vs* 2.97 gdl^{-1}). Again *EnR* group showed a negligible drop in albumin level (2.73 gdl^{-1} *vs* 2.77 gdl^{-1}) [Fig 11].

Impact of Diets of the subjects in the Subcategories based on NRI Score:

a. Impact of Diet on *EnR* study group:

The data on hemoglobin from the three subcategories (Sm, Mm and Wn) of the *EnR* study group showed a drop after EN stage [(Sm: 9.98 to 9.70 gdl^{-1}); (Mm: 12.40 to 11.00 gdl^{-1}); (Wn: 10.20 to 8.30 gdl^{-1})]. Total protein levels also showed a downward trend after EN stage [(Sm: 4.68 to 4.60 gdl^{-1}); (Mm: 4.63 to 4.60 gdl^{-1}); (Wn: 6.25 to 5.70 gdl^{-1})]. The albumin level of Sm subcategory showed an upward trend (2.54 to 2.74 gdl^{-1}), whereas a downward trend (2.88 to 2.63 gdl^{-1}) was observed in Mm subcategory. In the case of Wn subcategory, a drop in albumin level (3.40 to 2.72 g/dl) was noticed which is statistically significant ($p < 0.05$) [Table 9 (b)] [Fig 12].

b. Impact of Diet on *EnS* study group:

Hemoglobin levels of *EnS* study group showed an upward trend (10.86 to11.13 gdl^{-1}) in Sm subcategory whereas, Mm (13.37 to 11.92 gdl^{-1}) and Wn subcategories (10.86 to 10.50 gdl^{-1}) showed a downward trend after EN stage. An upward trend for total protein and albumin was noticed in Sm and Mm subcategory [(Sm: TP = 6.08 to 6.67 gdl^{-1}; Alb = 2.90 to 3.49 gdl^{-1}), (Mm: TP = 6.42 to 6.52 gdl^{-1}; Alb = 3.17 to 3.40 gdl^{-1})] whereas, Wn subcategory registered no change in the protein but a drop was observed in albumin level (TP = 6.30 to 6.36 gdl^{-1}; Alb = 3.66 to 3.26 gdl^{-1}) after EN stage [Table 9 (b)] [Fig 13].

c. Impact of diet on *EnM* study group:

The hemoglobin level recorded at pre-operative stage showed an upward trend in all three subcategories - Sm (10.06 to 10.33 gdl^{-1}), Mm (9.82 to 9.98 gdl^{-1}), Wn (9.90 to 10.55 gdl^{-1}) of the *EnM* study group. Total protein and albumin levels of Sm subcategory showed an upward trend (TP = 5.44 to 5.62 gdl^{-1}; Alb = 2.67 to 2.83 gdl^{-1}). However, the total protein and albumin levels of Mm subcategory showed a

Table 9 (a): Biochemical Levels at Different Stages of Nutrition in Study groups (n = 61)

Groups	Parameters						
	Hemoglobin ($12 - 17\ gdl^{-1}$)	Total Protein ($6.0 - 8.0\ gdl^{-1}$)	Albumin ($3.8 - 5.0\ gdl^{-1}$)	Sodium ($136 - 145\ mEqdl^{-1}$)	Potassium ($3.8 - 5.0\ mEqdl^{-1}$)	Creatinine ($0.6 - 1.2\ mgdl^{-1}$)	ALT ($5 - 40\ IUL^{-1}$)
Pre-operative Stage							
EnR (n = 21)	10.48 ±2.3	4.99 ±0.83	2.77 ±0.52	136.47 ±5.15	3.82 ±0.57	0.78 ±0.21	52.7 *(range: 10 - 285)*
EnS (n = 20)	11.37 ±2.1	6.18 ±1.07	3.10 ±0.71	134.40 ±8.12	4.38 ±0.86	1.17 ±0.36	47.67 *(range: 12 - 116)*
EnM (n = 20)	10.07 ±1.9	5.82 ±1.03	2.97 ±0.71	136.00 ±8.91	3.89 ±0.90	1.28 ±0.84	51.60 *(range: 1 - 160)*
After Post-operative EN Intake							
EnR (n = 21)	9.74 ↓ ±1.3	4.84 ↓ ±0.88	2.73 ↓ ±0.55	136.40 ±4.80	3.71 ±0.39	0.71 ±1.72	38.26 *(range: 10 - 168)*
EnS (n = 20)	11.20 ↓ ±1.7	6.60 ↑ @ ±0.95	3.44 ↑ @ ±0.73	135.00 ±3.67	3.85 ±0.54	1.23 ±0.17	41.87 *(range: 11 - 85)*
EnM (n = 20)	10.56 ↓ ±1.8	6.00 ↑ @ ±1.21	3.10 ↑ @ ±0.84	134.00 ±5.00	3.94 ±0.8	1.10 ±0.60	47.00 *(range: 11 - 155)*

@ Significantly higher level as compared to *EnR* (control) study group ($p < 0.05$)

↑↓ denotes increase or decrease in level as compared to pre-operative stage

Table 9 (b): Biochemical Levels at Different Stages of Nutrition in Subcategories

Study groups	Hemoglobin (12 – 17 g dl^{-1})			Total Protein (6.0 - 8.0 g dl^{-1})			Albumin (3.8 - 5.0 g dl^{-1})	
	Admission	EN Stage		Admission	EN Stage		Admission	EN Stage
EnR (n = 21)			*EnR* (n = 21)			*EnR* (n = 21)		
Sm (n = 13)	9.98 ±2.4	9.70 ↓ ±1.1	Sm (n = 13)	4.68 ± 0.44	4.60 ↓ ±0.50	Sm (n = 13)	2.54 ± 0.46	2.74 ↑ ± 0.61
Mm (n = 4)	12.40 ±2.0	11.00 ↓ ±1.5	Mm (n = 4)	4.63 ± 1.26	4.60 ↓ ±1.40	Mm (n = 4)	2.88 ± 0.15	2.63 ↓ ±0.10
Wn (n = 4)	10.20 ±1.6	8.30 ↓ ±1.1	Wn (n = 4)	6.25 ±0.31	5.70 ↓ ±0.80	Wn (n = 4)	3.40 ±0.47	2.72 * ±0.35
EnS (n = 20)			*EnS* (n = 20)			*EnS* (n = 20)		
Sm (n = 12)	10.86 ±2.3	11.13 ↑ ±1.8	Sm (n = 12)	6.08 ±1.03	6.67 ↑ ±1.01	Sm (n = 12)	2.90 ±0.68	3.49 ↑ ±0.80
Mm (n = 5)	13.37 ±1.0	11.92 ↓ ±1.2	Mm (n = 5)	6.42 ±0.88	6.52 ↑ ±1.99	Mm (n = 5)	3.17 ±0.23	3.40 ↑ ±0.85
Wn (n = 3)	10.86 ±0.9	10.50 ↓ ±1.7	Wn (n = 3)	6.30 ±1.73	6.36 ↑ ±0.32	Wn (n = 3)	3.66 ±0.68	3.26 ↓ ±0.23
EnM (n = 20)			*EnM* (n = 20)			*EnM* (n = 20)		
Sm (n = 11)	10.06 ±2.6	10.33 ↑ ±1.8	Sm (n = 11)	5.44 ±0.84	5.62 ↑ ±1.15	Sm (n = 11)	2.67 ±0.55	2.83 ↑ ±0.86
Mm (n = 5)	9.82 ±1.2	9.98 ↑ ±2.2	Mm (n = 5)	5.99 ±0.74	5.58 ↓ ±1.31	Mm (n = 5)	3.29 ±0.57	2.92 ↓ ±0.84
Wn (n = 4)	9.90 ±0.4	10.55 ↑ ±1.8	Wn (n = 4)	6.52 ±1.35	6.95 ↑ ±0.85	Wn (n = 4)	3.76 ±0.59	3.55 ↓ ±0.64

↑↓ denotes increase or decrease in level as compared to pre-operative stage
* Significantly lower than on admission $p < 0.05$

Fig 11: Impact of Diet on Total protein & Albumin(EnR, EnS, EnM study groups) (n = 61)

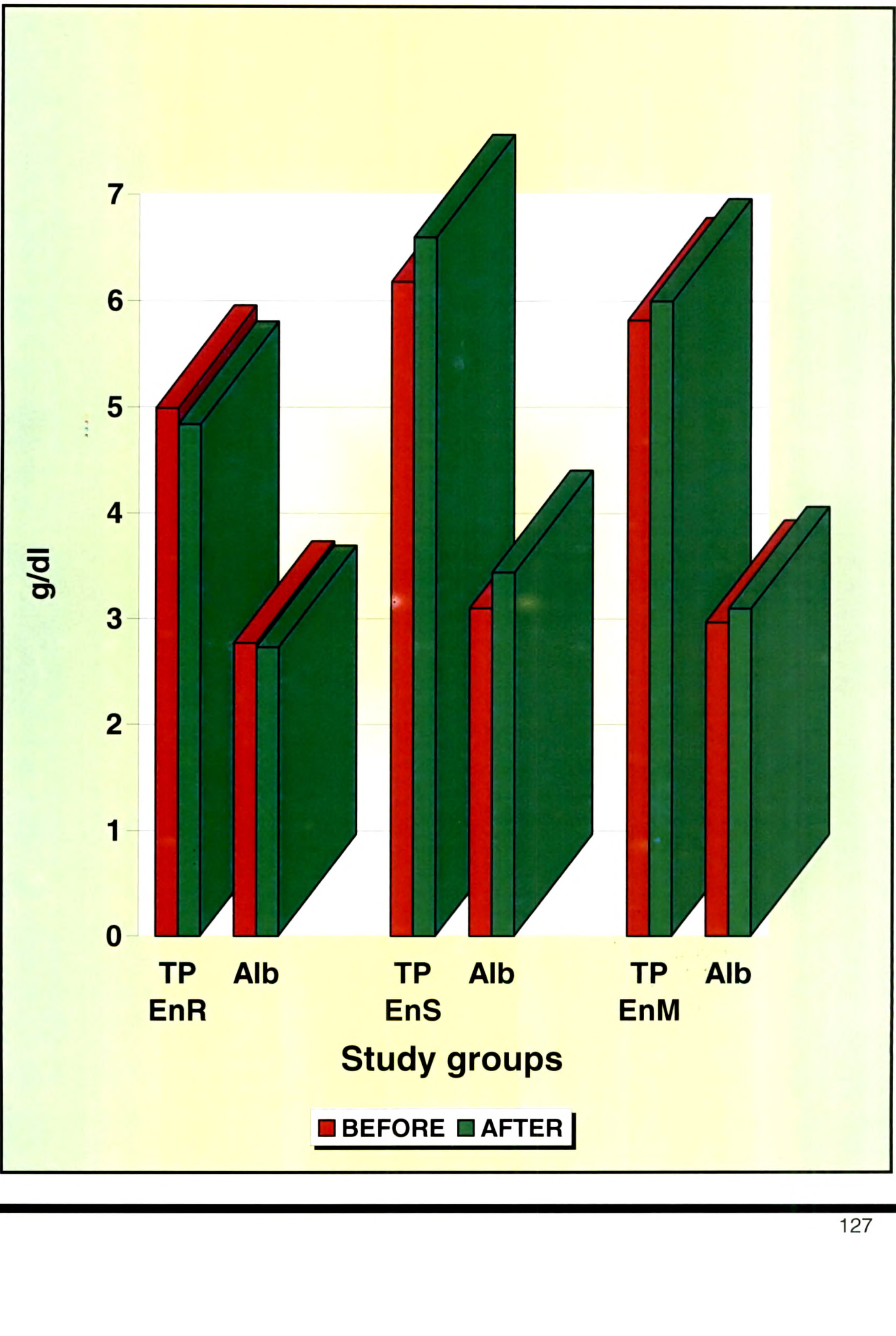


Fig 12: Impact of Diet on Total Protein & Albumin (EnR subcategories)

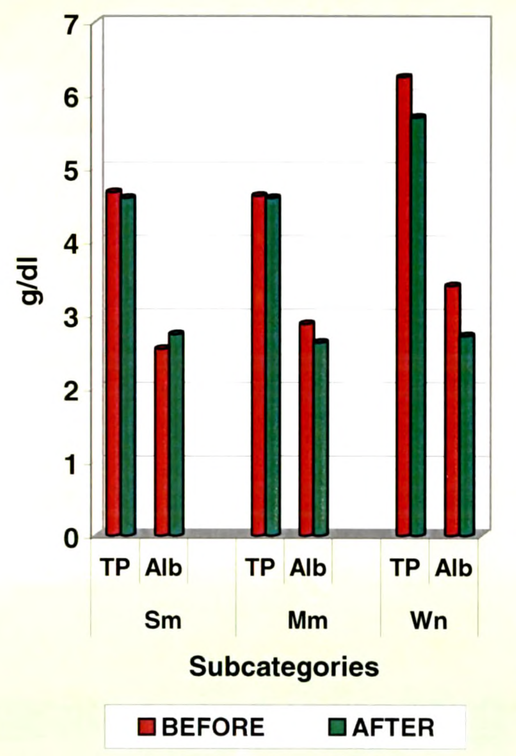


Fig 13: Impact of Diet on Total Protein & Albumin (EnS subcategories)

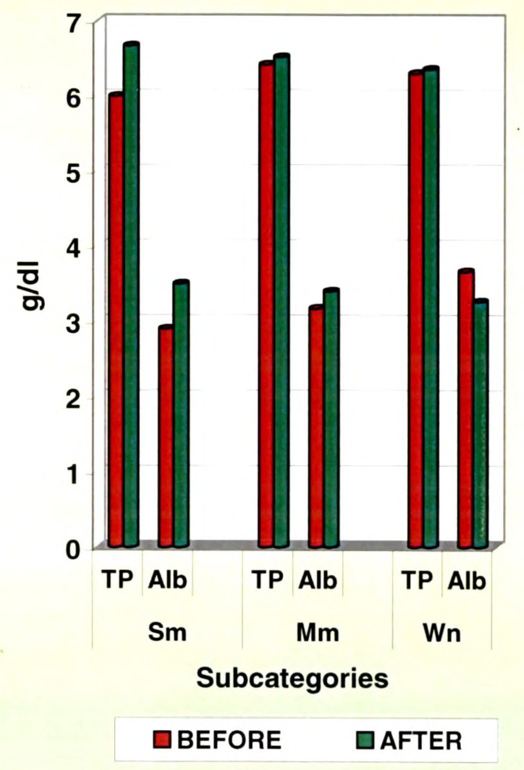
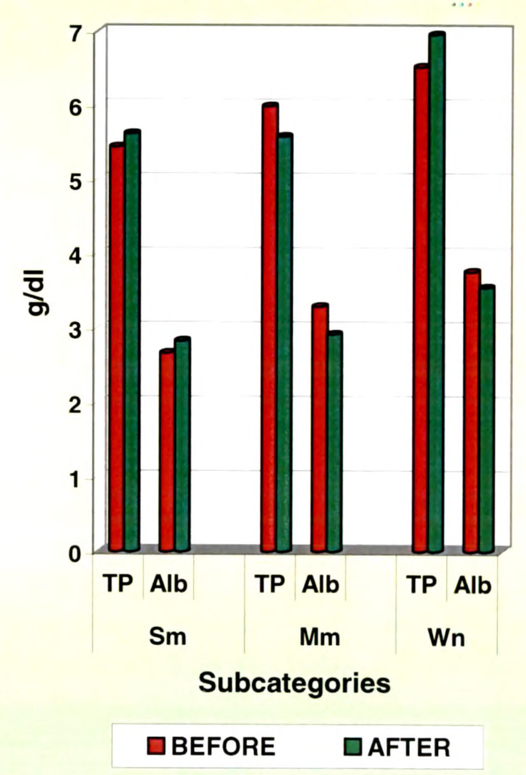


Fig 14: Impact of Diet on Total Protein & Albumin (EnM subcategories)



downward trend (TP = 5.99 to 5.58 gdl^{-1}; Alb = 3.29 to 2.92 gdl^{-1}), but in case of Wn subcategory, though total protein level showed an upward trend (TP = 6.52 to 6.95 gdl^{-1}), albumin level showed a drop (Alb = 3.76 to 3.55 g/dl) after EN stage [Table 9 (b)] [Fig 14].

Comparison among groups showed a significant improvement ($p < 0.05$) in total protein and albumin levels in *EnS* and *EnM* study groups [Mann Whitney U-test or Wilcoxon test] [Table 9 (a)]. Further, a significant improvement in total protein level was noticed in Sm subcategory of *EnS* study group compared to Sm subcategory in *EnR* study group ($p < 0.05$) [Table 9 (b)].

6.WEIGHT GAIN /LOSS ON DISCHARGE:

The data in Table 10 represents the impact of enteral diets on the study groups.
As compared to the time of admission to the time of discharge in the patients, the mean weight loss observed in *EnR* study group (5.05 Kg) was found to be statistically significant ($p < 0.001$). In the case of EnS study group, a small increase in weight (2.04 Kg), was observed during discharge as compared to the weight recorded at the time of admission and was noted to be statistically significant ($p < 0.05$). In case of *EnM* study group the mean weight loss of 1.45 Kg was noted which is statistically significant ($p < 0.001$) [Fig. 15].

Impact of Enteral Diets on Weight Gain /Loss in the Subcategories:

a. Impact of diet on *EnR* study group:

In general, weight loss was noted in *EnR* study group. The data also showed that the weight loss was 3.77 Kg (Sm), 8.00 Kg (Mm) and 6.25 Kg (Wn) in the respective three subcategories which were found to be statistically significant for Sm ($p < 0.05$) Mm ($p < 0.01$) and Wn ($p < 0.05$) subcategories [Table 11] [Fig. 16].

b. Impact of diet on *EnS* study group:

With respect to weight gain all the three subcategories from *EnS* study group recorded an improvement and out of the three subcategories the weight gain was

Table 10: Impact of Diets on Weight Gain/Loss in the Study Groups (n = 61)

	Particulars	Groups		
		EnR (n=21)	*EnS* (n=20)	*EnM* (n=20)
1	*Weight on Admission*	58.28 ± 12.79	51.15 ± 14.96	51.30 ± 14.41
2	*Weight On Discharge*	53.23 ±10.62	53.19 ± 13.94	49.80 ± 11.33
3	Difference in weight	(-) 5.05 Kg ***	(+) 2.04 Kg *	(-) 1.50 Kg***

* Significant gain of weight than on admission $p < 0.05$
*** Significant loss of weight than on admission $p < 0.001$

Table 11: Impact of Diets on Weight Gain/Loss in the Subcategories (n = 61)

Subcategories	Study Groups		
	EnR (n=21)	*EnS* (n=20)	*EnM* (n=20)
Weight On Admission: Sm	51.92 ± 9.65	45.38 ± 12.86	45.18 ± 11.27
Mm	70.00 ±15.03	54.00 ± 10.70	52.80 ± 12.53
Wn	67.25 ± 5.18	72.33 ± 7.50	65.75 ± 16.29
Weight On Discharge: Sm	48.15 ± 8.98	47.80 ± 11.67	46.18 ± 10.52
Mm	62.00 ± 10.09	55.50 ± 8.54	50.40 ± 12.38
Wn	61.00 ± 5.71	73.43 ± 7.50	64.00 ± 16.06
Difference in Weight : Sm	(-) 3.77 *	(+) 2.42 #	(+) 1.00 #
Mm	(-) 8.00 **	(+) 1.50	(-) 2.40 *
Wn	(-) 6.25 *	(+) 1.10	(-) 1.75 **

* Significant loss of weight than on admission $p < 0.05$
** Significant loss of weight than on admission $p < 0.01$
# Significant gain of weight than on admission $p < 0.05$

Fig 15: Impact of Diet on Weight Gain/Loss on Discharge (n = 61)

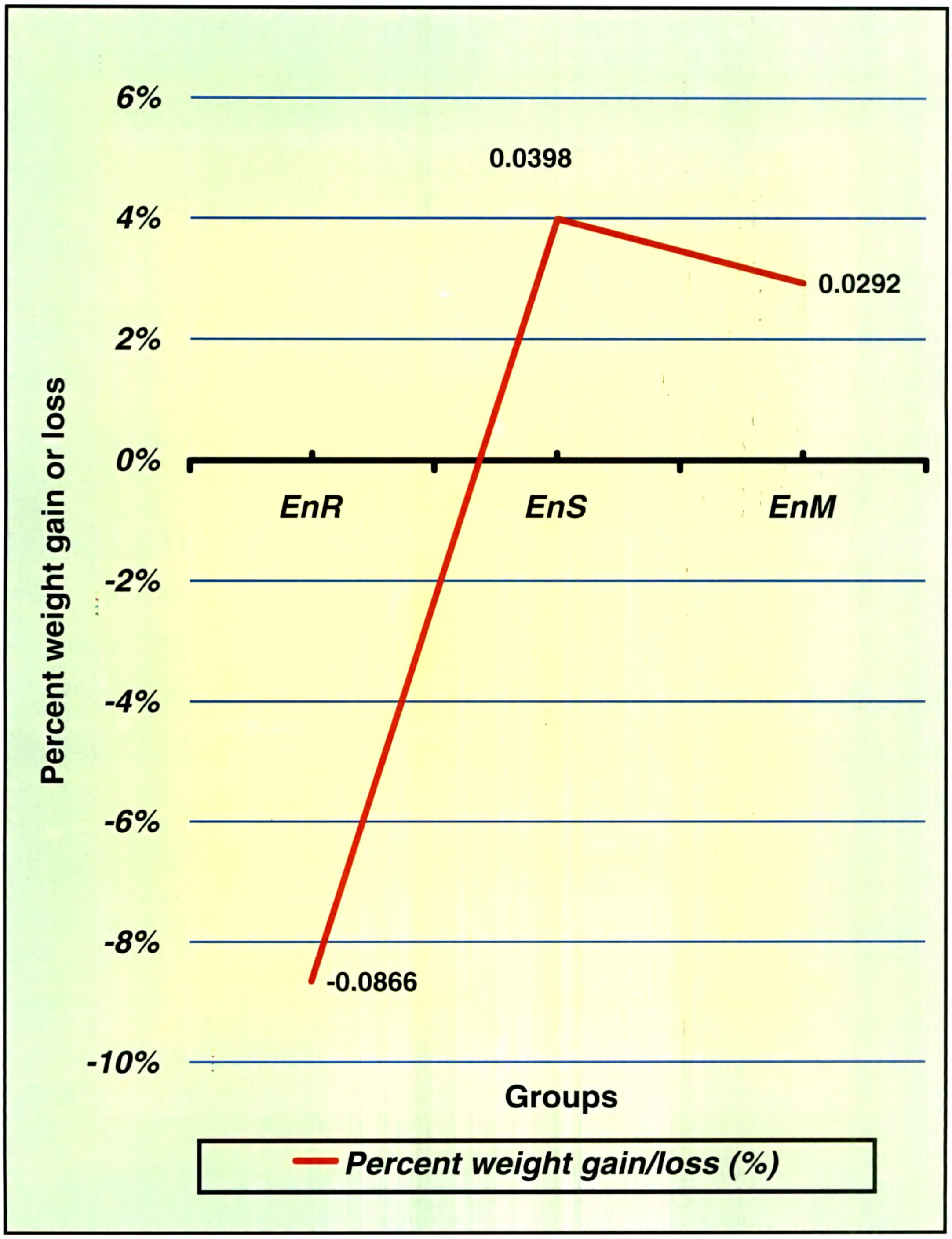
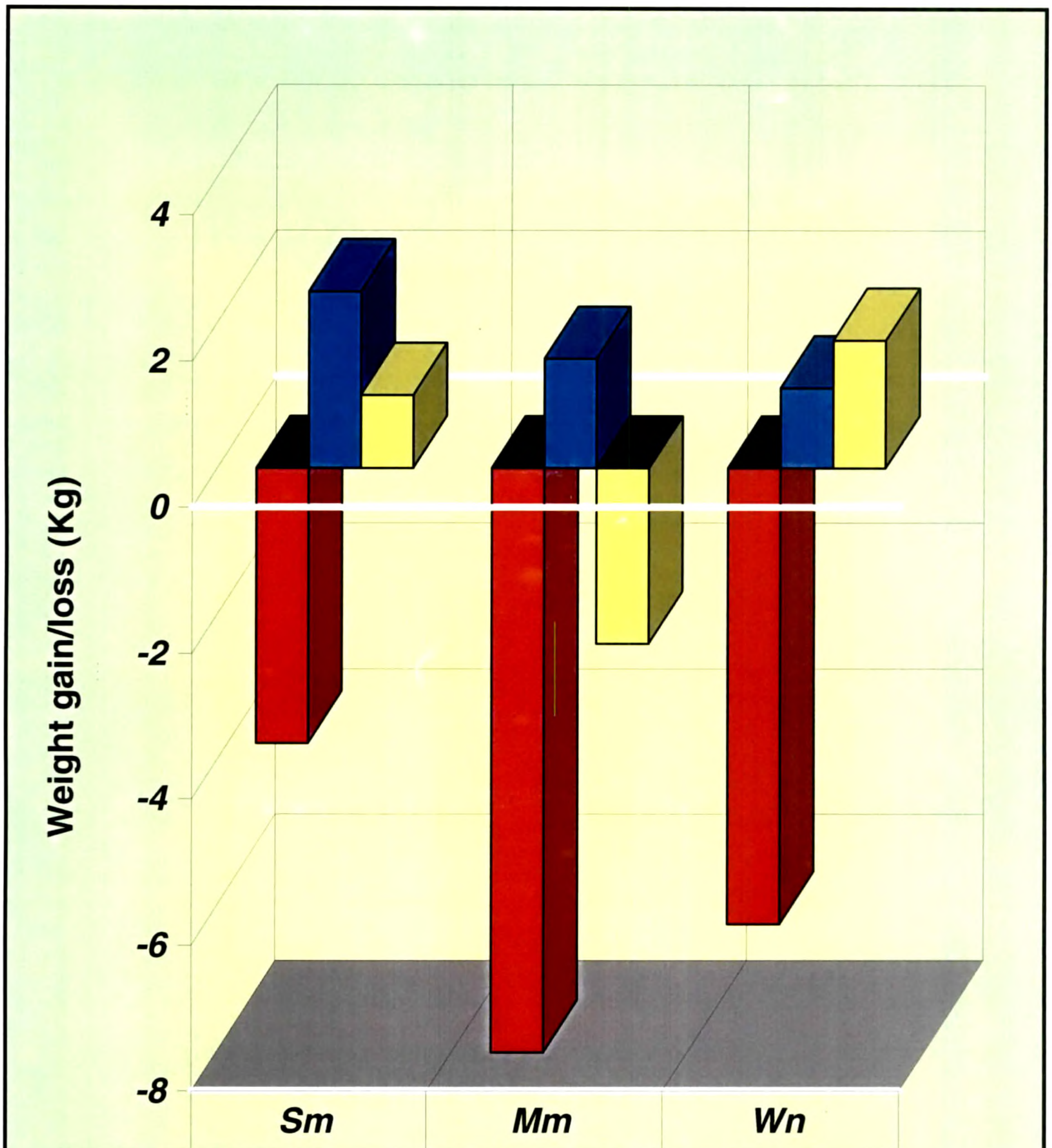


Fig 16: Weight gain/loss on Discharge (subcategories)



	Sm	Mm	Wn
EnR	-3.77	-8	-6.25
EnS	2.42	1.5	1.1
EnM	1	-2.4	1.75

much better in Sm (2.42 Kg) subcategory as compared to Mm (1.50 Kg) and Wn (1.10 Kg) subcategories and the weight gain was found to be statistically significant ($p < 0.05$) in Sm subcategory [Table 11] [Fig. 16].

c. Impact of diet on *EnM* study group:

Of the three subcategories from *EnM* study group only Sm subcategory recorded a small increase (1.0 Kg) in weight at the time of discharge as compared to the value observed at the time of admission. The weight gain was found to be statistically significant ($p < 0.05$). The other two subgroups recorded a loss of weight (Mm: 2.40 Kg; Wn: 1.75 Kg) at the time of discharge as compared to the value recorded at the time of admission. The weight loss was found to be statistically significant for Mm ($p < 0.05$) and Wn ($p < 0.01$) [Table 11] subcategories [Fig. 16].

7. LENGTH OF HOSPITAL STAY:

Impact of Enteral Diets on Length of Stay in study groups:

The data given in the Table 8 represents the length of hospital stay in all the groups. Pre-operative stay was 4.5 days, 3.0 days, and 2.6 days in *EnR*, *EnS* and *EnM* study groups thereby indicating that *EnR* group had a longer duration of pre-operative stay. Post-operative TPN feeding was 6.5 days, 4.7 days and 7.2 days for the three study groups, whereas a longer duration of post-operative enteral feeding was done for *EnR* (12.2 days), *EnS* (11.4 days) and *EnM* (11.1 days). With respect to total number days, the mean values were 22.4days in *EnR* study group, 16.5days in *EnS* and 16.7days in *EnM* study groups, respectively. Thus, *EnR* study group had significantly longer stay as compared to other two groups ($p < 0.05$) [Table 12] [Fig. 17].

Impact of Diets on Length of Stay in the Subcategories based on NRI Score:

a. Impact of diet on *EnR* study group:

The subcategory (Sm, Mm, Wn) of *EnR* study group had pre-operative stay of 3.9 days, 2.5 days, 8.3 days. Duration of post-operative TPN feeding for the

Table 12: Impact of Diets in Length of Stay in the Study Groups and Subcategories (n = 61)

	Particulars	Groups		
		EnR (n=21)	*EnS* (n=20)	*EnM* (n=20)
1	Pre-operative Stay	4.5	3.0	2.6
2	Post-operative TPN Stay	6.5	4.7	7.2
3	Post-operative EN Stay	12.2	11.4	11.1
4	Total stay upto EN	22.4 *	16.5	16.7
	** Significantly longer stay than* EnS *and* EnM *study groups p < 0.05*			
	Subcategories:	*EnR* (n=21)	*EnS* (n=20)	*EnM* (n=20)
	Pre-operative Stay: Sm	3.9 (n = 13)	3.0 (n = 12)	2.2 (n = 11)
	Mm	2.5 (n = 4)	2.5 (n = 5)	2.4 (n = 5)
	Wn	8.3 (n = 4)	3.7 (n = 3)	4.0 (n = 4)
	Post-operative EN Stay: Sm	12.1 (n = 13)	12.0 (n= 12)	11.2 (n = 11)
	Mm	13.5 (n = 4)	10.5 (n= 5)	12.0 (n = 5)
	Wn	11.0 (n = 4)	9.7 (n= 3)	9.8 (n = 4)
	Total Stay: Sm	19.9 (n = 13)	16.7 (n= 12)	15.8 (n =11)
	Mm	22.8 (n = 4)	17.0 (n= 5)	19.2 (n = 5)
	Wn	30.0 (n = 4) *	15.0 (n= 3)	15.8 (n = 4)
	* Significantly longer stay than *EnS* and *EnM* p < 0.05			

Fig 17: Impact of Diet on Length of Stay (LOS) (n = 61)

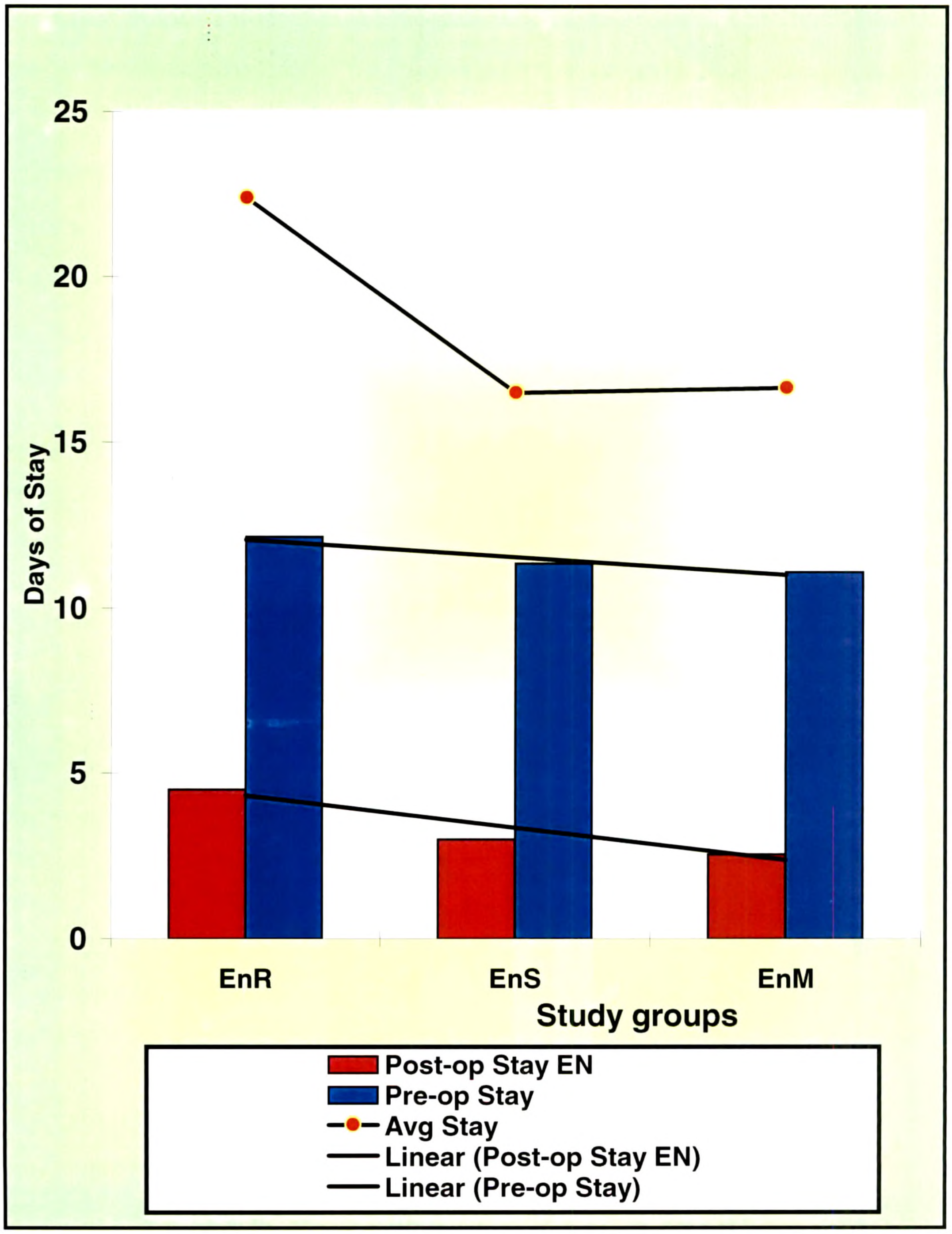


Fig 18 a: Impact of Diet on LOS
(EnR subcategories)

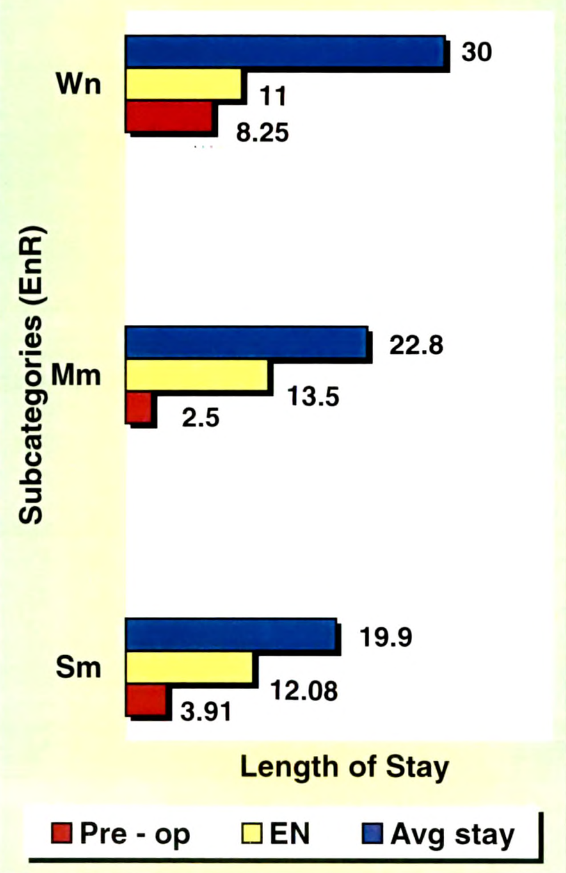


Fig 18 b: Impact of Diet on LOS
(EnS subcategories)

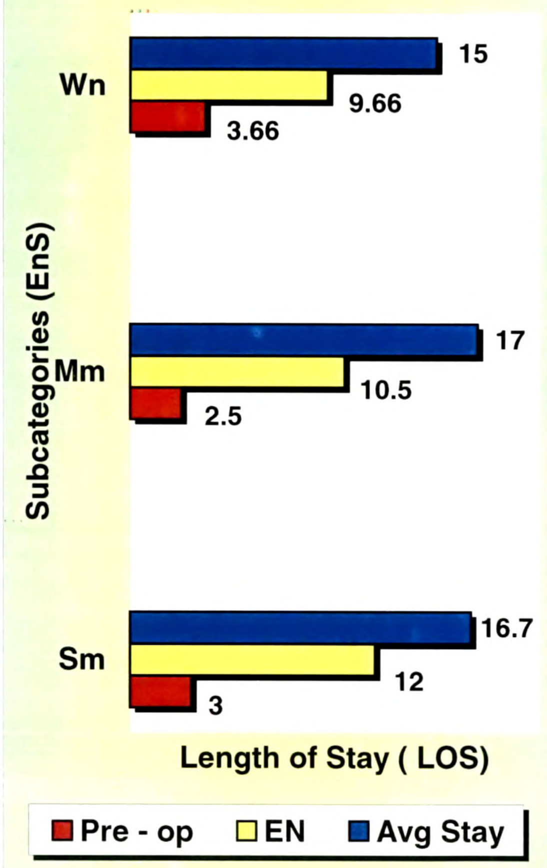
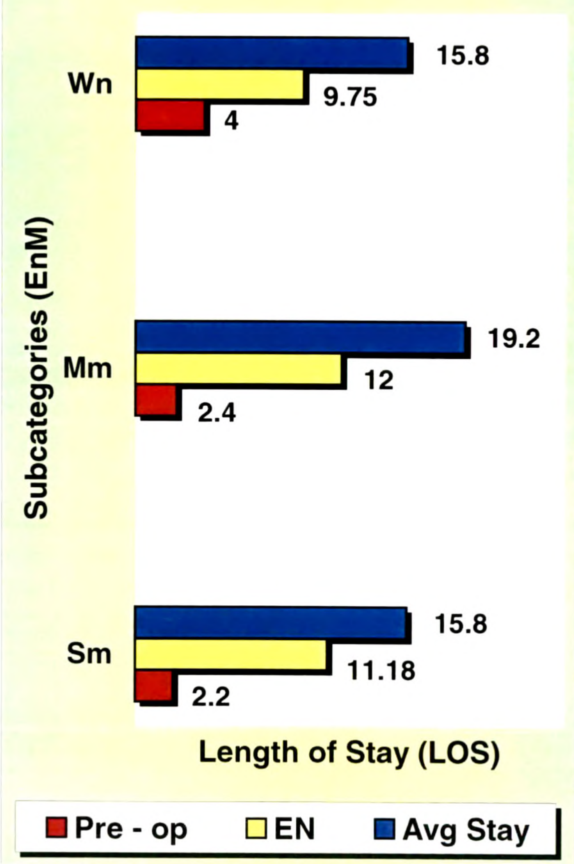


Fig 18 c: Impact of Diet on LOS
(EnM subcategories)



subcategories Sm, Mm, and Wn of *EnR* study group were 3.9 days, 2.5 days, and 8.3 days. Post-operative EN feeding was done for 12.1 days, 13.5 days, 11.0 days in Sm, Mm and Wn subcategories and average stay up to EN stage was 19.9 days, 22.8 days, 30.0 days in *EnR* study group. Thus, Wn subcategory had significantly longer stay up to EN stage ($p < 0.05$) as compared to other two subcategories in *EnR* study group [Table 12] [Fig 18 a].

b. Impact of diet on *EnS* study group:

The subcategories (Sm, Mm, Wn) of *EnS* study group had pre-operative stay of 3.0days, 2.5days, 3.7 days. Duration of post-operative TPN feeding for the subcategories Sm, Mm, Wn were 3.0days, 2.5days, 3.7days. Post-operative EN feeding was done for 12.0 days (Sm), 10.5 days (Mm), 9.7 days (Wn) and an average stay upto EN stage was 16.7days, 17.0 days, 15.0 days respectively, in *EnS* study group. Thus Wn subcategory had shorter stay as compared to Sm subcategory [Table 12] [Fig 18 b].

c. Impact of diet on *EnM* study group:

The number of days of hospitalisation at pre-operative stage was found to be 2.2days, 2.4days, and 4.0days. Duration of post-operative TPN feeding for the subcategories Sm, Mm, Wn were 2.2 days, 2.4 days, 4.0 days. Duration of post-operative EN feeding was done for 11.2 days, 12.0 days, 9.8 days in Sm, Mm, Wn subcategories of *EnM* study group. The number of days of hospitalisation till the completion of EN stage was found to be 15.8 days, 19.2 days, 15.8 days in Sm, Mm, Wn subcategories. It is evident from the data that the Mm subcategory had a longer duration of hospital stay as compared to other two subgroups in *EnM* study group [Table 12] [Fig 18 c].

SECTION III

Enteral Glutamine Enriched Routine Hospital Enteral diet (G*EnR*) *Vs* Kitchen-based Polymeric Protein Rich Enteral diets *with* Glutamine (G*EnS and GEnM*)

In this section, the patients were given kitchen based polymeric enteral diets with sources of protein either *soy* (*GEnS*, group 5) or *milk* (*GEnM*, group 6) with *substrate enriched enteral glutamine* and control group (*GEnR*, group 4) was given routine hospital enteral diet *with substrate enriched enteral glutamine*. These diets were delivered through transnasal or enterostomy tubes during post-operative enteral stage to the surgical gastrointestinal patients as per predetermined protocol.

RESULTS:

1. DEMOGRAPHIC PROFILE:

The demographic profile of the hospitalised patients is shown in Table 13.
The mean age of the study subjects (n = 45) in the three groups, *GEnR*, *GEnS*, *GEnM* were 48.3 years (range: 26 – 65 years), 40.1years (range: 21 - 60 years) and 45.9 years (range: 25 - 70 years) respectively. In the present study, there were 12 types of gastrointestinal (G.I) diseases. *GEnR* study group had 8 types, *GEnS* study group had 7 types and *GEnM* study group had 10 types of diseases. Of these 64.4 % were of upper G.I diseases, 8.9 % were of lower G.I diseases and 26.7 % were of miscellaneous types.

2. NUTRITIONAL ASSESSMENT:

(i) Anthropometric Profile:

The anthropometric assessment and nutritional risk index rating of the subjects were done soon after hospitalisation and the data is presented in Table 14.

a. Height and Weight: The average height and weight of all the subjects on admission ranged from 143.0 - 176.0 cm (mean: 160.0 cm) and 25.0 - 91.0 Kg (mean: 53.5 kg).

b. Weight Loss on Admission: More than 10 % of weight loss as compared to usual body weight (UBW) was noticed in 35.6 % of the patients on admission, whereas a loss of less than 10 % of UBW was noticed in 33.3 % of the subjects.

c. Body Mass Index (BMI): There were four categories of patients in the study group as: underweight, normal, overweight and obese based on BMI classification. The **'underweight'** category [*BMI: ≤ 18.5*] patients were 20.0 % (*GEnR*), 26.7 % (*GEnS*) and 20.0 % (*GEnM*) patients; **'normal'** category [*BMI: 18.5 - 24.9*] patients were 46.7 % (*GEnR*), 46.7 % (*GEnS*) and 73.3 % (*GEnM*) whereas, 20.0 % (*GEnR*), 13.3% (*GEnS*) and 6.7% (*GEnM*) patients were in **'overweight'** category [*BMI: 24.9 - 29.9*]. Another 13.3 % (*GEnR*) and 13.3% (*GEnS*) patients were in **'obese'** category [*BMI: ≥ 29.9*].

(ii) Nutritional Risk Index (NRI):

NRI was calculated as per the formula highlighted in the materials and methods (p. 94). The mean values for the three groups 2.66 gdl^{-1}, 2.85 gdl^{-1} and 3.04 gdl^{-1}, were found to be lower as compared to their normal levels (Alb: 3.8-5.0g/dl). The NRI score rated 46.7 % (*GEnR*), 60.0 % (*GEnS*) and 53.3 % (*GEnM*) as severely malnourished (*Sm*) subcategory. Mild-moderately malnourished (*Mm*) subcategory comprised of 40.0 %, 26.7 %, 26.7 % and well-nourished (*Wn*) subcategory comprised of 13.3 %, 13.3 % and 20.0 % for the respective *GEnR*, *GEnS*, *GEnM* study groups. Thus an average of 53.3 % of the total study patients enrolled were rated as Sm subcategory. The study group as per NRI score was further rated into

Table 13: Demographic Profile (n = 45)

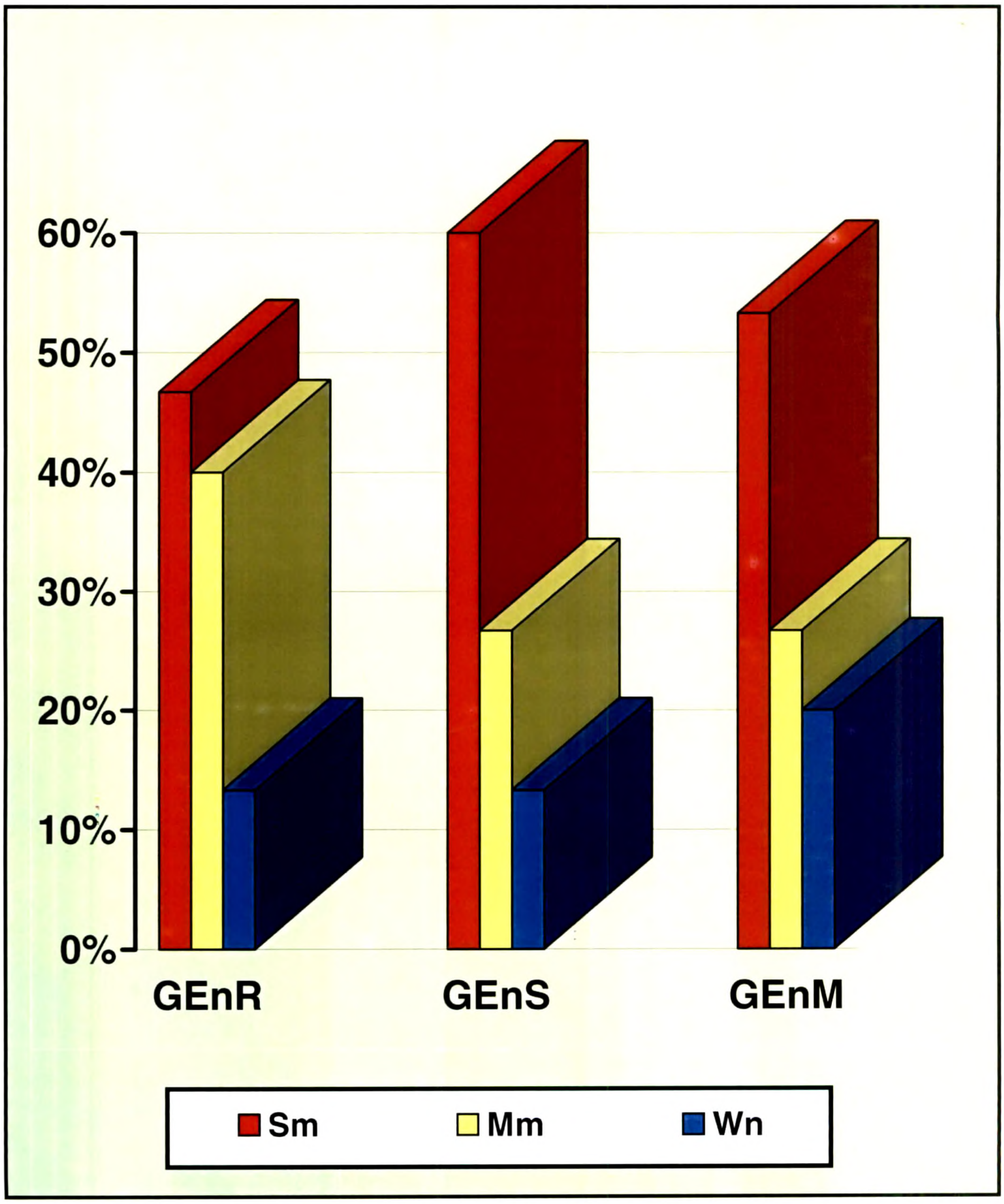
	Particulars	Groups		
		GEnR	*GEnS*	*GEnM*
I.	Subjects (Male+Female)	15(9M+6F)	15(12M+3F)	15(10M+5F)
II.	Mean Age	48.3	40.1	45.9
III.	Diagnosis			
	Upper G.I Diseases (64.4%)			
	Oesophageal Stricture	1	-	1
	Ca-oesophagus	2	3	1
	Duodenal perforation	1	-	1
	Duodenal malignancy	-	1	3
	Acute pancreatitis	4	6	2
	Adenocarcinoma of pancreas	1	1	1
	Lower G.I Diseases (8.9%)			
	Ca-colon	2	-	1
	Fecal fistula	1	-	-
	Miscellaneous (26.7%)			
	Intestinal obstruction	3	2	1
	Congestive spleenomegaly	-	-	2
	Acute liver	-	1	2
	CBD-obstruction	-	1	-

Table 14: Nutritional Status On Admission (n = 45)

	Particulars	Groups		
		GEnR (n=15)	*GEnS* (n=15)	*GEnM* (n=15)
I	Height (cm) (range:143 – 176cm)	159.0 ± 7.2	159.7 ± 3.7	158.6 ± 4.1
II	Weight (Kg) (range: 25 - 91 Kg)	59.6 ± 14.3	56.7 ± 18.5	53.0 ± 10.3
III	Loss of weight:			
	<10% of UBW (mean loss: 33.3 %)	3(20.0 %)	5(33.3 %)	7(46.7 %)
	>10% of UBW (mean loss: 35.6%)	4(26.7 %)	6(40.0 %)	6(40.0 %)
IV	Body Mass Index (BMI)			
	≤18.5 (Underweight category)	3(20.0 %)	4(26.7 %)	3(20.0 %)
	18.5-24.9 (Normal category)	7(46.7 %)	7(46.7 %)	11(73.3 %)
	24.9-29.9 (Overweight category)	3(20.0 %)	2(13.3 %)	1(6.7 %)
	≥29.9 (Obese category)	2(13.3 %)	2(13.3 %)	-
V	Mean serum albumin (gdl^{-1})	2.66 #	2.85 #	3.04 #
VI	Nutritional Risk Index (NRI)			
	Severely malnourished (Sm)	7(46.7 %)	9(60.0 %)	8(53.3 %)
	Mild-moderately malnourished(Mm)	6(40.0 %)	4(26.7 %)	4(26.7 %)
	Well nourished (Wn)	2(13.3 %)	2(13.3 %)	3(20.0 %)

Albumin level at nutritional risk (normal levels : 3.8-5.0 gdl^{-1})

Fig 19: Nutritional Risk Index
(n = 45)



subheadings such as Sm, Mm, Wn subcategories for better interpretation of results [Fig 19].

3. NUTRIENT INTAKE:

The patients were on their own diet during the pre-operative stage. In the post-operative stage (Post-operative TPN and EN) based on surgical procedure needed, patients were kept on TPN followed by EN or directly on EN. Supplementations of feeding formulas with *subsequent substrate enriched glutamine* were done during post-operative enteral nutrition (EN) stage.

The diet intakes (pre-operative stage and post-operative EN stage along with their requirements for the study groups are presented in Table 15 and 16 (a,b,c).

(i) Pre-operative Nutrient Intake by the Study groups:

Pre-operative nutrient intake in general for the study groups (*GEnR*, *GEnS*, *GEnM*) were adequate compared to their requirements. The average calorie, carbohydrate, protein, fat were 1,822.2 Kcal, 328.1 g, 46.0 g, 48.1 g in *GEnR* group, whereas intakes of 1,768.7 Kcal, 284.9 g, 44.5 g, 55.3 g were observed in *GEnS* study group and 1,909.0 Kcal, 344.8 g, 58.3 g, 57.3g in *GEnM* study group respectively. In general calorie intake by the respective three groups were adequate, but protein intake was found to be low which is statistically significant ($p < 0.05$) as compared to their requirements [Table 15].

Nutrient Intake by the Subjects in the Subcategories Based on NRI Score:

a. *GEnR* Study group:

The mean values of each group were- energy: 1,984.1 Kcal, carbohydrate: 360.3 g, protein: 47.2 g, fat: 48.1 g in Sm subcategory, energy: 1,580.0 Kcal, carbohydrate : 265.6 g, protein: 43.5 g, fat: 49.2 g in Mm subcategory and energy: 1,982.0 Kcal, carbohydrate: 404.1 g, protein: 49.2 g, fat: 44.5 g. Thus, Sm and Mm subcategories had significantly low intake of protein ($p < 0.05$), whereas significantly low intake of calories was noted for Mm subcategory compared to their requirements. A downward trend of protein intake was observed in Wn subcategory as compared to their requirement [Table 16 (a, b, c)].

b. *GEnS* Study group:

In case of *GEnS* study group, the subcategories Sm (energy: 1,829.4 Kcal, carbohydrate: 296.6 g, protein: 46.6 g, fat: 58.1 g), Mm (energy:1,639.7 Kcal, carbohydrate:202.3 g, protein: 38.8 g, fat: 50.2 g) and Wn (energy:1,754.0 Kcal, carbohydrate: 397.2 g, protein: 46.6 g, fat: 52.7 g) had adequate intake of calories, but significantly a low intake of protein was noted by Sm and Mm subcategories ($p < 0.05$) [Table 16 (a, b, c)].

c. *GEnM* Study group:

The calorie and carbohydrate intakes were adequate in Sm subcategory (energy: 1,853.2 Kcal, carbohydrate: 355.8 g, protein: 63.3 g, fat: 51.0 g), Mm (energy: 1,942.8 Kcal, carbohydrate : 377.7 g, protein : 52.7 g, fat : 67.1 g)and Wn (energy: 2,016.4 Kcal, carbohydrate:271.9 g, protein : 52.2 g, fat:61.1 g) subcategories in *GEnM* study groups compared to their requirement. However, the protein intake was found to be lower in all the patients. [Table 16 (a, b, c)] and was significantly lower in Mm subcategory ($p < 0.05$) [Table 16 (a, b, c)].

(ii) Post-operative nutrient Intake by the Study Groups:

The data on post-operative diet intake is presented in Table 15.

During post-operative EN stage the calorie and protein intake by *GEnR* study group was significantly lower ($p < 0.05$) as compared to their requirement (energy: 1,305.8 Kcal, carbohydrate: 230.6 g, protein: 42.7 g, fat: 32.1 g). A better intake was noted in *GEnS* study group (energy: 1,853.0 Kcal, carbohydrate: 257.0 g, protein: 103.3 g, fat: 37.1 g) and *GEnM* study group (energy:1,766.0 Kcal, carbohydrate : 243.9 g, protein: 93.2 g, fat: 60.0 g) as compared to their requirements.

The data from the Table 15 also indicates that the energy intake of *GEnR* study group (1,305.8 Kcal *vs* 1,822.2 Kcal) was significantly lower in post-operative EN stage as compared to pre-operative stage ($p < 0.05$). Energy intake was better (1,853.0 Kcal *vs* 1,768.7 Kcal) in *GEnS* whereas in *GEnM* (1766.0 Kcal *vs* 1909.0 Kcal) intake was lower in post-operative EN as compared to the pre-operative stage.

Carbohydrate intake was low in all the study groups. A lower intake of protein was noted in *GEnR* study group (42.7 g *vs* 46.0 g). In *GEnS* study group (103.3 g *vs* 44.5 g) and *GEnM* study group (93.2 g *vs* 58.3 g) protein intake was found to be higher as compared to pre-operative stage.

Nutrient Intake by the Subjects in the subcategories based on NRI Score:

a. *GEnR* Study group:

The subcategories of the *GEnR* study group recorded considerably lower intakes of major nutrients thereby resulting in lower energy. All the three subcategories, Sm, Mm, Wn had lower intakes of calories and protein as compared to their requirements and a low protein intake was prominent in Sm (energy: 1,295.3 Kcal, carbohydrate: 227.4 g, protein: 36.5 g, fat: 24.8g) and Mm (energy: 1,271.0Kcal, carbohydrate: 243.0g, protein: 51.1g, fat: 31.8g) subcategories compared to their requirements [Table 16 (a,b,c)].

b. *GEnS* Study group:

The subcategories of *GEnS* study group recorded better intakes of major nutrients thereby resulting adequate intakes of energy. The energy and protein intakes were adequate for Sm as compared to their requirement (energy: 1,876.7 Kcal, carbohydrate: 255.6 g, protein: 111.3 g, fat: 40.6 g). Mm subcategory had adequate intake of energy whereas, protein intake was significantly low as compared to their requirement (energy: 1,756.7 Kcal, carbohydrate: 259.7 g, protein: 93.1 g, fat: 34.5 g). Wn (energy: 1,939.0 Kcal, carbohydrate: 258.0 g, protein: 87.6 g, fat: 26.3 g) subcategory had lower intake of protein and fat as compared to their requirement [Table 16 (a,b,c)].

c. *GEnM* Study group:

The energy and protein intake in Sm (energy: 1,687.9 Kcal, carbohydrate: 232.1 g, protein: 88.8 g, fat: 57.7 g), Mm (energy: 1,854.8 Kcal, carbohydrate: 260.6 g, protein: 99.7 g, fat: 63.9 g) Wn (energy: 1,856.8 Kcal, carbohydrate: 253.3 g, protein:

Table-15: Assessment of Nutrient Intake: *Average Requirements Vs Average Intakes* (n = 45)

Study groups	Energy (Kcal)	Carbohydrate (g)	Protein (g)	Fat (g)
REQUIREMENT				
GEnR (n=15)	1759.9 ±284.5	255.8 ±41.0	92.1 ±15.1	40.3 ±5.8
GEnS (n=15)	1851.3 ±221.1	271.1 ±33.6	97.5 ±11.5	41.0 ±6.8
GEnM (n=15)	1754.4 ±199.6	254.3 ±30.0	92.1 ±10.1	41.0 ±5.4
AVERAGE INTAKES				
Pre-operative Stage				
GEnR (n=15)	1822.2 ±510.9	328.1 ±133.4	46.0 * ±14.3	48.1 ±18.0
GEnS (n=15)	1768.7 ±615.6	284.9 ±133.0	44.5 * ±20.4	55.3 ±29.7
GEnM (n=15)	1909.0 ±465.7	344.8 ±173.3	58.3 * ±28.2	57.3 ±26.5
Post-operative EN Stage				
GEnR (n=15)	1305.8 * Ψ ±311.9	230.6 ±89.5	42.7 * ±12.9	32.1 # ±17.7
GEnS (n=15)	1853.0 @ ±274.8	257.0 ±41.4	103.3 # @ ±37.0	37.1 ±21.4
GEnM (n=15)	1766.0 @ ±169.9	243.9 ±31.2	93.2 @ ±9.5	60.0 ±12.5

* Significantly lower intake than the required intake $p<0.05$
Ψ Significantly lower intake than the pre-operative stage $p<0.05$
Significantly higher intake than the pre-operative stage $p<0.05$
@ Significantly higher intake as compared to control group (GEnR) ($p<0.05$)

Table 16 (a): Assessment of Nutrient Intake: *Average Requirements Vs Average Intakes of 'Severely Malnourished' Subcategory (Sm) as per NRI score*

Study Groups	Energy (Kcal)	Carbohydrate (g)	Protein (g)	Fat (g)
REQUIREMENT				
GEnR (n = 7)	1641.9 ±261.7	238.1 ±37.9	86.2 ±13.7	38.0 ±5.5
GEnS (n = 9)	1832.5 ±183.8	266.9 ±26.4	96.2 ±9.6	40.2 ±5.3
GEnM (n = 8)	1642.2 ±195.4	236.9 ±29.6	85.6 ±8.8	37.9 ±4.0
AVERAGE INTAKE				
	Pre-operative Stage			
GEnR (n = 7)	1984.1 ±318.3	360.3 ±112.4	47.2* ±9.6	48.1 ±17.9
GEnS (n = 9)	1829.4 ±611.1	296.6 ±105.8	46.6 * ±22.6	58.1 ±31.6
GEnM (n = 8)	1853.2 ±327.5	355.8 ±194.9	63.3 ±37.2	51.0 ±24.7
	Post-operative EN Stage			
GEnR (n = 7)	1295.3 $^{\Psi}$ ±335.6	227.4 ±82.4	36.5* $^{\Psi}$ ±10.2	24.8 ±13.7
GEnS (n = 9)	1876.7 ±324.0	255.6 ±50.8	111.3 $^{\#@}$ ±46.4	40.6 ±22.7
GEnM (n = 8)	1687.9 ±188.5	232.1 ±34.3	88.8 $^{@}$ ±10.9	57.7 ±8.9

* Significantly lower intake than the required intake $p < 0.05$
$^{\Psi}$ Significantly lower intake than the pre-operative stage $p < 0.05$
$^{\#}$ Significantly higher intake than the pre-operative stage $p < 0.05$
$^{@}$ Significantly higher intake as compared to control group (GEnR) ($p < 0.05$)

Table 16 (b): Assessment of Nutrient Intake: *Average Requirements Vs Average Intakes of 'Mild-moderately Malnourished' Subcategory (Mm) as per NRI score*

Study Groups	Energy (Kcal)	Carbohydrate (g)	Protein (g)	Fat (g)
REQUIREMENT				
GEnR (n = 6)	1951.0 ±258.7	284.3 ±35.3	101.7 ±14.8	44.0 ±5.4
GEnS (n = 4)	1844.2 ±358.9	274.9 ±56.8	97.9 ±18.5	40.4 ±11.2
GEnM (n = 4)	1820.0 ±98.1	266.1 ±12.4	96.6 ±4.4	44.8 ±6.4
AVERAGE INTAKE				
	Pre-operative Stage			
GEnR (n = 6)	1580.0 * ±697.1	265.3 ±136.2	43.5 * ±21.2	49.2 ±22.6
GEnS (n = 4)	1639.7 ±694.5	202.3 ±130.1	38.8 * ±14.1	50.2 ±35.6
GEnM (n = 4)	1942.8 ±735.2	377.7 ±187.4	52.7 ±5.6	67.1 ±33.5
	Post-operative EN Stage			
GEnR (n = 6)	1271.0 * ±353.9	243.0 ±117.5	51.1 * ±12.6	31.8 ±17.2
GEnS (n = 4)	1756.7 ±177.1	259.7 ±27.0	93.1 * # ±8.1	34.5 Ψ ±24.0
GEnM (n = 4)	1854.8 ±48.9	260.6 ±16.7	99.7 # ±3.8	63.9 ±16.0

* Significantly lower intake than the required intake $p < 0.05$
Ψ Significantly lower intake than the pre-operative stage $p < 0.05$
\# Significantly higher intake than the pre-operative stage $p < 0.05$

Table 16 (c): Assessment of Nutrient Intake: *Average Requirements Vs Average Intakes of ' Well nourished' Subcategory (Wn) as per NRI score*

Study Groups	Energy (Kcal)	Carbohydrate (g)	Protein (g)	Fat (g)
REQUIREMENT				
GEnR (n = 2)	1600.0 ±141.4	232.00 ±20.50	84.0 ±7.4	37.3 ±3.3
GEnS (n = 2)	1950.0 ±70.71	282.8 ±10.3	102.4 ±3.7	45.5 ±1.7
GEnM (n = 3)	1966.1 ±68.0	285.1 ±9.9	103.2 ±3.6	44.4 ±0.8
AVERAGE INTAKE				
	Pre-operative Stage			
GEnR (n = 2)	1982 ± 173.9	404.1 ±195.6	49.2 ±1.7	44.5 ±5.2
GEnS (n = 2)	1754.0 ± 878.2	397.2 ±231.6	46.6 ±30.6	52.7 ±18.0
GEnM (n = 3)	2016.4 * ±547.9	271.9 ±117.6	52.2 ±21.6	61.1 ±26.9
	Post-operative EN Stage			
GEnR (n = 2)	1447.0 ±108.9	204.7 ±1.8	39.6 ±14.1	58.5 ±1.2
GEnS (n = 2)	1939.0 ±257.2	258.0 ±32.5	87.6 ±14.8	26.3 ±13.0
GEnM (n = 3)	1856.8 ±146.8	253.3 ±32.1	96.0 ±5.4	60.9 ±19.6
* Significantly higher intake than the requirement p< 0.05				

96.0 g, fat: 60.9 g) subcategories of *GEnM* study group were found to be adequate as compared to their requirements [Table-16 (a,b,c)].

In general, the important macronutrient *i.e* protein intake was significantly higher in Sm, Mm subcategories belonging to *GEnS* study group and Mm subcategory of *GEnM* study group as compared to pre-operative stage. Even though the levels recorded were not statistically significant, there was an improvement in the protein intake by Sm, Mm subcategories of *GEnM* and Wn subcategory of *GEnS* also. In case of *GEnR* study group *i.e* control group there was no appreciable increase in protein intake at *post-operative stage as compared to pre-operative stage.*

Comparison in adequacies of post-operative intake among groups further reflected that energy and protein intakes were significantly higher in *GEnS* and *GEnM* study groups compared to *GEnR* study group ($p < 0.05$) [Mann Whitney U-test or Wilcoxon test] [Table 11]. However, protein intake in Sm subcategory in *GEnM* study group was found significantly higher compared to Sm subcategory of *GEnR* study group ($p < 0.05$) [Table 12(a)]. Such an observation was not found on subgroup analysis for the other two study groups *(GEnR, GEnS).*

4. FEEDING RELATED COMPLICATIONS:

Feeding related complications were more for *GEnR* (tube occlusion, abdominal distension, diarrhoea) study group. *GEnM* study group had complaints of abdominal distension and diarrhoea but with lesser frequency whereas *GEnS* study group had very few complaints of abdominal distension only. Feed related complications in *GEnR* study group was more in Sm subcategory followed by Mm and Wn subcategories. In EN stage, these complications were predominantly related to symptoms of gastrointestinal intolerances (aspirates, vomiting, abdominal bloating and diarrhoea).

5. OUTCOME MEASURES:

(i) Impact of Diets on Biochemical Parameters in the Study Groups:

The biochemical profile (before and after supplementation of diets) of the patients from different study groups is presented in Table 17(a).

In the post-operative stage, hemoglobin levels did not alter much in all the three study groups except *GEnS* [(*GEnR*: 10.62 gdl^{-1} *vs* 10.39 gdl^{-1}); (*GEnS*: 11.50 gdl^{-1} *vs* 10.76 gdl^{-1}); (*GEnM*: 10.50 gdl^{-1} *vs* 11.10 gdl^{-1})]. In case of total protein, *GEnS* study group showed improvement and *GEnM* showed slight improvement after post-operative EN stage compared to pre-operative stage [(*GEnS*: 6.20 *vs* 5.53 gdl^{-1}); (*GEnM*: 6.29 gdl^{-1} *vs* 6.23 gdl^{-1})]. *GEnR* study group showed a negligible improvement in total protein (5.01 gdl^{-1} *vs* 5.00 gdl^{-1}). Similarly, improvement in albumin level is observed for *GEnS* (3.20 gdl^{-1} *vs* 2.85 gdl^{-1}) whereas, a slight improvement is noted for *GEnM* (3.10 gdl^{-1} *vs* 3.04 gdl^{-1}) after post-operative EN as compared to pre-operative stage [Fig 20].

Impact of Diets of the Subjects in the Subcategories based on NRI Score:

a. Impact of Diet on *GEnR* Study group:

The data on hemoglobin from the two subcategories (Sm, Mm) showed a drop after EN stage whereas, an upward trend was noted in Wn subcategory of the *GEnR* study group [(Sm: 9.64 to 9.48 gdl^{-1}); (Mm: 11.66 to 11.63 gdl^{-1}); (Wn: 9.20 to 11.55 gdl^{-1})]. Total protein level showed a downward trend after EN stage in Sm and Mm subcategories [(Sm: 4.7 to 4.45 gdl^{-1}); (Mm: 5.55 to 5.23 gdl^{-1})] whereas, an upward trend was noted in Wn subcategory (TP = 6.25 to 6.30 gdl^{-1}). Albumin level in Sm (Alb = 2.11 to 2.41 gdl^{-1}), and Wn (Alb = 3.75 to 3.80 gdl^{-1}) subcategories showed an upward trend whereas, a downward trend was observed for Mm (Alb = 2.95 to 2.76 gdl^{-1}) subcategory [Table 17 (b)] [Fig 21].

b. Impact of Diet on *GEnS* Study group:

Hemoglobin level of *GEnS* study group showed an upward trend (10.74 to 11.23 gdl^{-1}) in Sm, Mm (11.1 to 12.55 gdl^{-1}) and Wn subcategories (10.10 to 10.95 gdl^{-1}) after EN stage. An upward trend for total protein (TP) and albumin (Alb) was also noted in

Table 17 (a): Biochemical Levels at Different Stages of Nutrition in Study groups (n = 45)

Groups	Parameters						
	Hemoglobin ($12-17\ gdl^{-1}$)	Total Protein ($6.0-8.0\ gdl^{-1}$)	Albumin ($3.8-5.0\ gdl^{-1}$)	Sodium ($136-145\ mEqdl^{-1}$)	Potassium ($3.8-5.0\ mEqdl^{-1}$)	Creatinine ($0.6-1.2\ mgdl^{-1}$)	ALT ($5-40\ IUL^{-1}$)
Pre-operative Stage							
GEnR (n =15)	10.39 ±2.5	5.00 ±1.18	2.66 ±0.76	136.43 ±6.72	3.74 ±0.64	1.33 ±0.56	36.76 *(range: 15-57)*
GEnS (n =15)	10.76 ±1.7	5.53 ±0.83	2.85 ±0.39	134.60 ±9.85	3.69 ±0.64	1.00 ±0.42	128.48 *(range: 10-1027)*
GEnM (n =15)	11.10 ±2.4	6.23 ±1.04	3.04 ±0.75	137.00 ±6.25	3.90 ±0.60	1.07 ±0.52	32.80 *(range: 7-49)*
After Post-operative EN Intake							
GEnR (n =15)	10.62 ↑ ±2.0	5.01 ↑ ±1.28	2.73 ↑ ±0.72	137.65 ±5.13	3.98 ±0.58	0.90 ±0.46	28.80 *(range: 15-40)*
GEnS (n =15)	11.50 ↑ ±1.9	6.20 ↑@ ±1.10	3.20 ↑ @ ±0.57	137.28 ±4.70	3.87 ±0.59	0.87 ±0.46	32.92 *(range: 19-50)*
GEnM (n =15)	10.50 ↓ ±1.6	6.29 ↑ @ ±1.18	3.10 ↑ ±0.70	136.00 ±4.81	4.28 ±0.59	0.96 ±0.36	24.66 *(range: 12-47)*

@ Significantly higher level as compared to *GEnR* (control) study group ($p < 0.05$)

↑↓ denotes increase or decrease in level as compared to pre-operative stage

Table 17 (b): Biochemical Levels at Different Stages of Nutrition in Subcategories

Study groups	Hemoglobin ($12 - 17\ g\ dl^{-1}$)		Study groups	Total Protein ($6.0 - 8.0\ g\ dl^{-1}$)		Study groups	Albumin ($3.8 - 5.0\ g\ dl^{-1}$)	
	Admission	EN Stage		Admission	EN Stage		Admission	EN Stage
GEnR (n = 15)			*GEnR* (n = 15)			*GEnR* (n = 15)		
Sm (n = 7)	9.64 ±2.2	9.48 ↓ ±1.2	Sm (n = 7)	4.70 ±0.73	4.45 ↓ ±0.73	Sm (n = 7)	2.11 ±0.40	2.41 ↑ ±0.44
Mm (n = 6)	11.66 ±2.8	11.63 ↓ ±1.8	Mm (n = 6)	5.55 ±0.28	5.23 ↓ ±1.17	Mm (n = 6)	2.95 ±0.61	2.76 ↓ ±0.61
Wn (n = 2)	9.20 ±1.7	11.55 ↑ ±3.6	Wn (n = 2)	6.25 ±2.47	6.30 ↑ ±2.68	Wn (n = 2)	3.75 ±0.63	3.80 ↑ ±1.13
GEnS (n = 15)			*GEnS* (n = 15)			*GEnS* (n = 15)		
Sm (n = 9)	10.74 ±1.9	11.23 ↑ ±2.2	Sm (n = 9)	5.27 ±0.71	5.70 ↑ ±0.7	Sm (n = 9)	2.63 ±0.24	2.83 ↑ ±0.26
Mm (n = 4)	11.10 ±2.0	12.55 ↑ ±1.7	Mm (n = 4)	5.62 ±0.61	7.00 ↑ ±1.26	Mm (n = 4)	3.07 ±0.36	3.70 ↑ ±0.58
Wn (n = 2)	10.10 ±0.6	10.95 ↑ ±1.1	Wn (n = 2)	6.55 ±1.34	7.05 ↑ ±1.20	Wn (n = 2)	3.42 ±0.11	3.80 ↑ ±0.28
GEnM (n = 15)			*GEnM* (n = 15)			*GEnM* (n = 15)		
Sm (n = 8)	10.9 ±2.4	10.57 ↓ ±1.5	Sm (n = 8)	5.64 ±0.61	5.91 ↑ ±0.94	Sm (n = 8)	2.66 ±0.48	3.03 ↑ ±0.69
Mm (n = 4)	11.1 ±3.1	11.4 ↑ ±1.5	Mm (n = 4)	6.50 ±0.73	6.35 ↓ ±1.43	Mm (n = 4)	3.13 ±0.6	3.20 ↑ ±1.0
Wn (n = 3)	12.6 ±2.6	9.4↓ ±0.4	Wn (n = 3)	6.95 ±1.34	6.60 ↓ ±1.30	Wn (n = 3)	3.68 ±0.96	2.70 ↓ ±0.14
↑↓ denotes increase or decrease in level as compared to pre-operative stage								

Fig 20 : Impact of Diet on Total protein & Albumin (GEnR,GEnS,GEnM study groups) (n = 45)

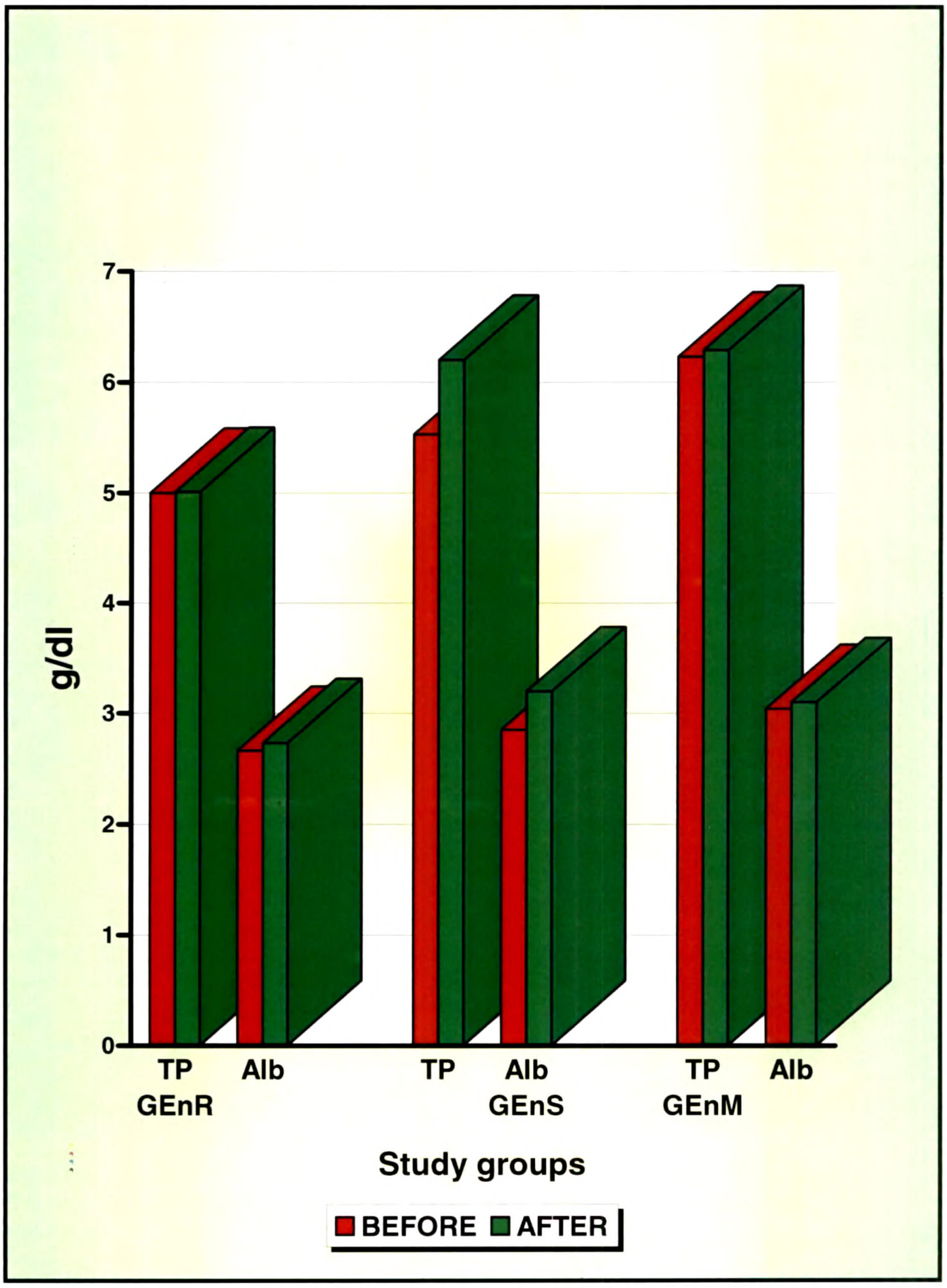


Fig 21: Impact of Diet on Total Protein & Albumin (GEnR subcategories)

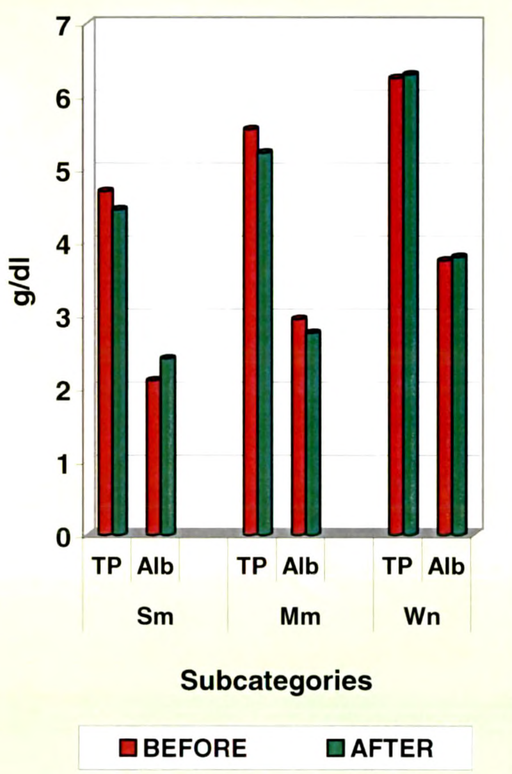


Fig 22: Impact of Diet on Total Protein & Albumin (GEnS subcategories)

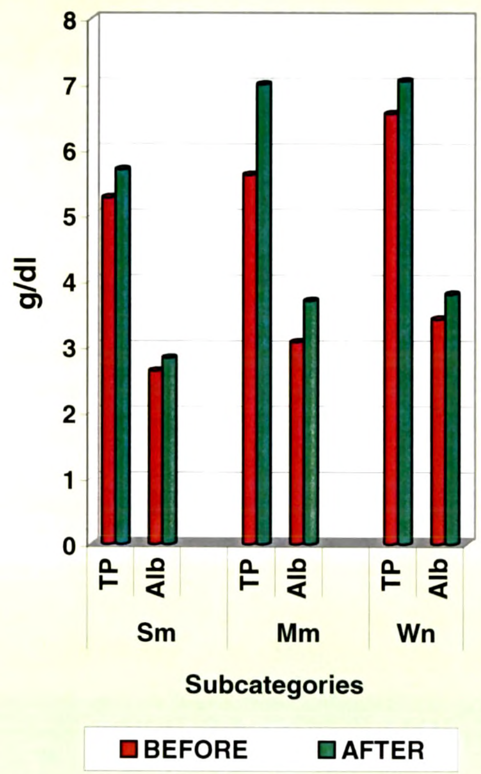
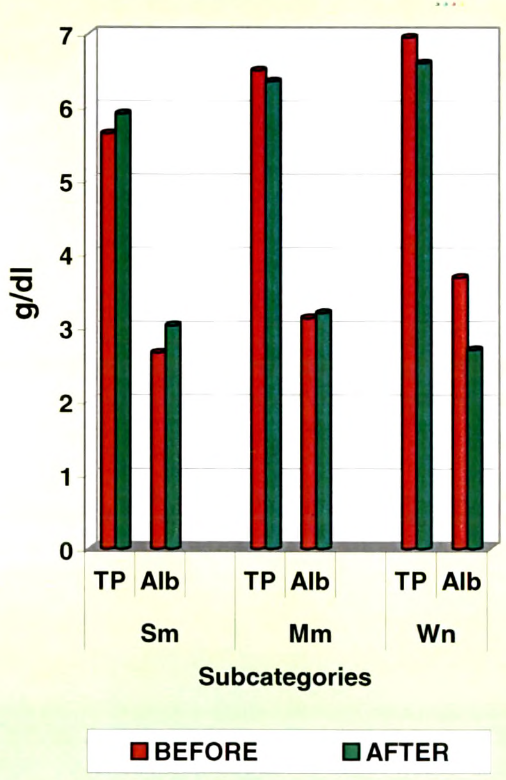


Fig 23: Impact of Diet on Total Protein & Albumin (GEnM subcategories)



Sm, Mm and Wn subcategories [(Sm: TP = 5.27 to 5.70 gdl^{-1} ; Alb = 2.63 to 2.83 gdl^{-1}); (Mm: TP = 5.62 to 7.00 gdl^{-1}; Alb = 3.07 to 3.70 gdl^{-1}); (Wn: TP = 6.55 to 7.05 gdl^{-1}; Alb = 3.42 to 3.80 gdl^{-1})] after EN Stage [Table 17(b)] [Fig 22].

c. Impact of diet on *GEnM* study group:

The level of hemoglobin level showed a drop in post-operative stage in all the three subcategories. Total protein and albumin levels of Sm subcategory showed an upward trend (TP = 5.64 to 5.91 gdl^{-1}; Alb = 2.66 to 3.03 gdl^{-1}). In case of Mm and Wn subcategories, a downward trend was noticed for the above parameters [Table 17 (b)] [Fig 23].

Comparison between groups showed a significant improvement ($p < 0.05$) in total protein and albumin levels in *GEnS* and only total protein level in *GEnM* study groups [Mann Whitney U-test or Wilcoxon test] [Table 17(a)].

6.WEIGHT GAIN /LOSS ON DISCHARGE:

The data in the Table 18 represents the impact of enteral diets in the study groups. As compared to the time of admission to the time of discharge, patients registered loss of weight in *GEnR* study group (1.60 Kg) ($p < 0.001$). In case of *GEnS* and *GEnM* study groups, a small increase in weight was observed during discharge as compared to the weight recorded at the time of admission [(*GEnS*: 2.20 Kg); (*GEnM*: 1.36Kg)], which is statistically significant ($p < 0.05$) [Fig 24].

Impact of Enteral Diets on Weight Gain /Loss in Subcategories:

a. Impact of diet on *GEnR* Study group:

In general, weight loss was noted in *GEnR* study group. The data also showed that the weight loss was 1.15 Kg (Sm), 2.83 Kg (Mm), 0.25 Kg (Wn) in the respective three subcategories, which was found to be statistically significant for Sm ($p < 0.001$) and Mm ($p < 0.05$) subcategories [Table 19] [Fig 25].

Table 18: Impact of Diets on Weight Gain/Loss in the Study Groups (n = 45)

	Particulars	Groups		
		GEnR (n = 15)	*GEnS* (n = 15)	*GEnM* (n = 15)
1	*Weight on Admission*	59.60 ± 14.27	56.73 ± 18.53	53.00 ± 10.33
2	*Weight On Discharge*	58.20 ± 12.80	58.93 ± 17.42	54.36 ± 9.06
3	Difference in weight	(-) 1.60 Kg ***	(+) 2.20 Kg *	(+) 1.36 Kg *

* Significant gain in weight as compared to admission $p < 0.05$
*** Significant loss in weight as compared to admission $p < 0.001$

Table 19: Impact of Diets on Weight Gain/Loss in the Subcategories (n = 45)

Subcategories		Study Groups		
		GEnR (n=15)	*GEnS* (n=15)	*GEnM* (n=15)
Weight On Admission:	Sm	49.28 ± 12.77	46.66 ± 13.71	47.75 ± 14.64
	Mm	70.33 ± 7.22	68.25 ± 16.86	59.75 ± 12.95
	Wn	63.50 ±12.02	79.00 ±14.64	58.00 ± 3.04
Weight On Discharge:	Sm	48.13 ±10.95	49.90 ± 12.95	49.83 ± 8.83
	Mm	67.50 ± 6.28	68.55 ± 3.04	58.42 ± 7.75
	Wn	63.25 ± 13.08	80.35 ± 10.58	61.00 ± 5.56
Difference in Weight :	Sm	(-) 1.15 ***	(+) 3.24 #	(+) 2.08 #
	Mm	(-) 2.83 *	(+) 0.30 #	(-) 1.33
	Wn	(-) 0.25	(+) 1.35	(+) 3.00 #

* Significant loss in weight as compared to admission $p < 0.05$
*** Significant loss in weight as compared to admission $p < 0.001$
# Significant gain in weight as compared to admission $p < 0.05$

Fig 24: Impact of Diet on Percent weight gain/loss (Study groups) (n = 45)

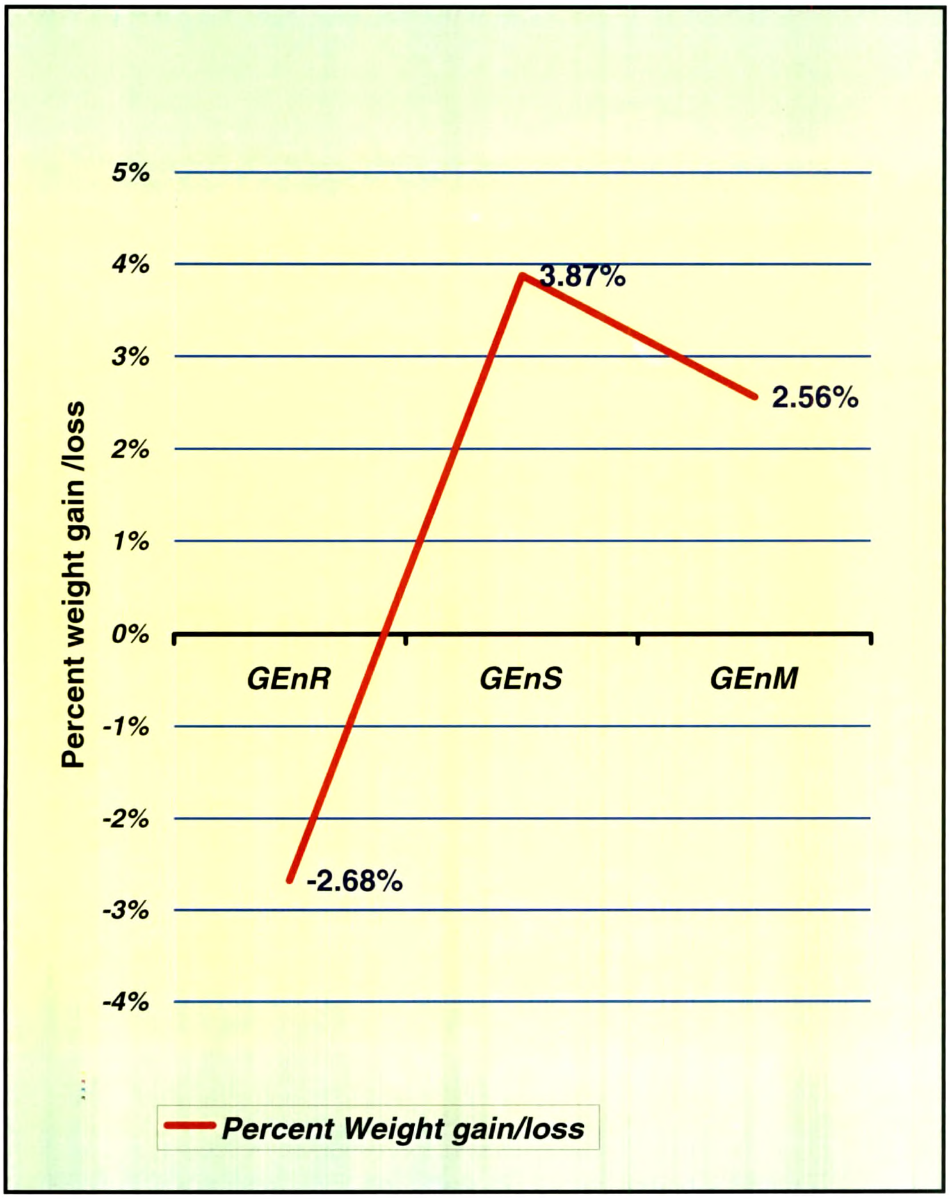
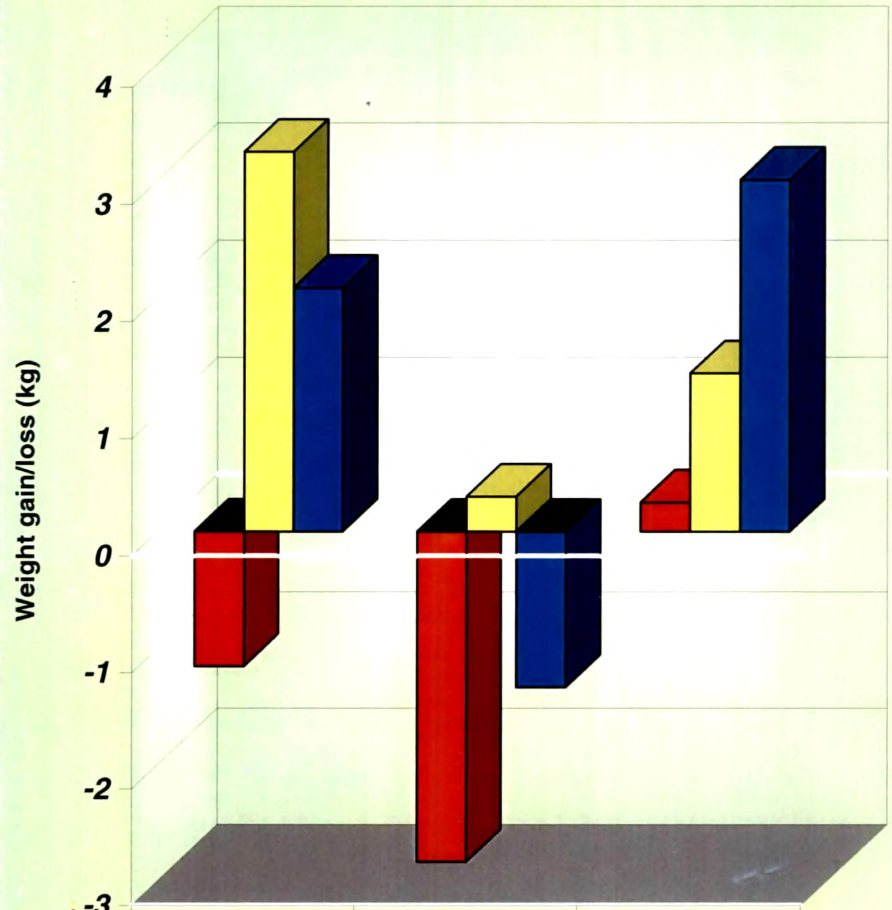


Fig 25: Weight gain/loss on Discharge (subcategories)



	Sm	Mm	Wn
GEnR	-1.15	-2.83	0.25
GEnS	3.24	0.3	1.35
GEnM	2.08	-1.33	3

b. Impact of diet on *GEnS* Study group:

With respect to weight gain all the three subcategories from *GEnS* study group recorded an improvement. Out of the three subgroups, the weight gain was much better in Sm subcategory [3.24 Kg] and was statistically significant ($p < 0.05$). Mm subcategory recorded increase in weight [0.30 Kg] and was statistically significant ($p < 0.05$). Wn subcategory also recorded increase in weight [1.35 Kg] at the time of discharge and was found to be statistically non-significant [Table 19] [Fig 25].

c. Impact of diet on *GEnM* Study group:

Of the three subcategories from *GEnM* study group only Sm and Wn subcategories recorded a small increase in weight [(Sm: 2.08 Kg) and (Wn: 3.00 Kg)] at the time of discharge as compared to the value observed at the time of admission. Weight gain in Sm and Wn subcategory was found to be statistically significant ($p < 0.05$). The Mm subcategory recorded a loss of weight [1.33 Kg] at the time of discharge as compared to the value recorded at the time of admission [Table 19] [Fig 25].

7. LENGTH OF HOSPITAL STAY:

Impact of Enteral Diets on Overall Length of Stay in Study Groups:

The data given in the Table 20 represents the length of hospital stay in all the groups. Pre-operative stay was 2.9 days, 1.7 days, and 2.6 days in *GEnR*, *GEnS* and *GEnM* study groups thereby indicating that *GEnR* group had a longer duration of pre-operative stay. Post-operative TPN feeding was 4.5 days, 7.7 days and 1.8 days for the three study groups whereas a longer duration of post-operative enteral feeding was done for *GEnR* (15.0 days), *GEnS* (11.2 days) and *GEnM* (11.6 days). With respect to total number days, the mean values were 18.7 days by *GEnR* study group, 14.5 days in *GEnS* and 14.4 days in *GEnM* respectively. *GEnS* and *GEnM* study groups had significant shorter stay compared to *GENR* study group ($p < 0.05$)
[Fig 26].

Impact of Diets on Overall Length of Stay in Subcategories Based On NRI:

a. Impact of diet on *GEnR* Study group:

The subcategories (Sm, Mm, Wn) of *GEnR* study groups had pre-operative stay of 2.4 days, 4.0 days, 1.5 days. Duration of post-operative TPN feeding for the subcategories Sm, Mm, Wn in *GEnR* study group were 2.4 days, 4.0 days, 1.5 days. Post-operative EN feeding was done for 14.3 days, 14.3 days, 16.0 days in Sm, Mm, Wn subcategories of *GEnR* study group and average stay up to EN stage was 18.0 days, 19.8 days, 17.5 days Thus, Wn subcategory had shorter duration of stay as compared to Sm and Mm subcategories [Table 20] [Fig 27 a].

b. Impact of diet on *GEnS* Study group:

The subcategories(Sm, Mm, Wn) of *GEnS* study group had pre-operative stay of 2.1 days, 1.0 day, 1.5 days. Duration of post-operative TPN feeding for the subcategories Sm, Mm, Wn were 2.1 days, 1.0 day, 1.5 days in *GEnS* study group. Post-operative EN feeding was done for 11.5 days (Sm), 11.3 days (Mm), 9.5 days (Wn) for *GEnS* study group and average stay up to EN stage was 15.8 days, 13.3 days, 11.0 days respectively. Thus Sm subcategory had longer stay compared to other two subcategories [Table 20] [Fig 27 b].

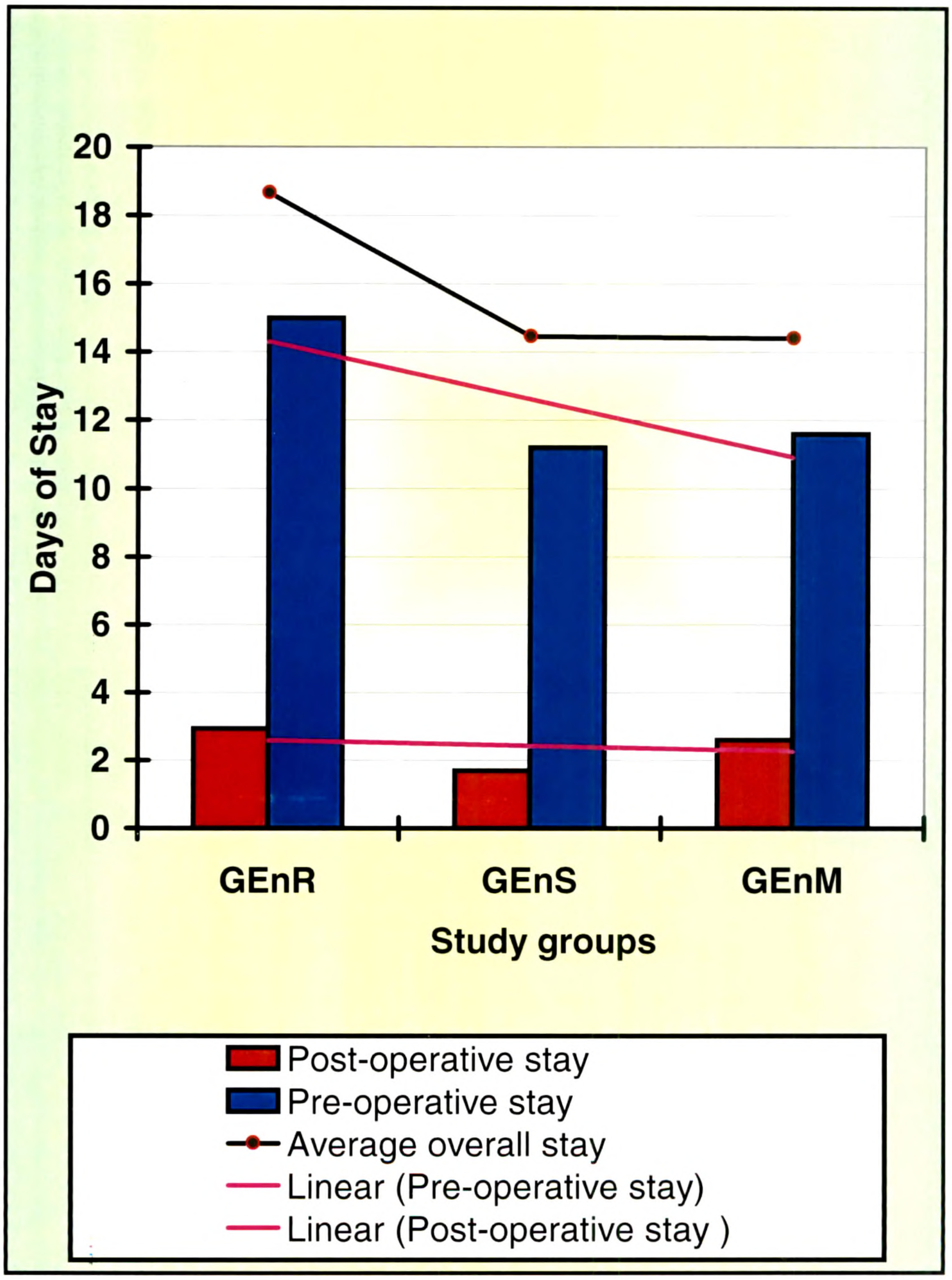
c. Impact of diet on *GEnM* Study group:

The number of days of hospitalisation at pre-operative stage was found to be 3.1 days, 2.3 days, 1.7 days. Duration of post-operative TPN feeding for Sm, Mm, Wn subcategories were 3.1 days, 2.3 days, 1.7days in *GEnM* study groups. Post-operative EN feeding was done for 10.6 days (Sm), 11.8 days (Mm), 14.0 days (Wn) for *GEnM* study group. The number of days of hospitalisation till the completion of EN stage was found to be 13.7 days, 14.0 days, 16.7 days in Sm, Mm, Wn subcategories. It is evident from the data that the Wn subcategory had a longer duration of hospital stay as compared to other two subcategories in *GEnM* study group [Table 20] [Fig 27 c].

Table 20: Impact of Diets in Length of Stay in the Study Groups and Subcategories (n = 45)

	Particulars	Groups		
		GEnR (n =15)	*GEnS* (n =15)	*GEnM* (n =15)
1	Pre-operative Stay	2.9	1.7	2.6
2	Post-operative TPN Stay	4.5	7.7	1.8
3	Post-operative EN Stay	15.0	11.2	11.6
4	Total stay upto EN	18.7	14.5 *	14.4 *
	** Significantly shorter stay than GEnR study group p < 0.05*			
	Subcategories:	*GEnR* (n=15)	*GEnS* (n=15)	*GEnM* (n=15)
	Pre-operative Stay: Sm	2.4 (n = 7)	2.1 (n = 9)	3.1 (n = 8)
	Mm	4.0 (n = 6)	1.0 (n = 4)	2.3 (n = 4)
	Wn	1.5 (n = 2)	1.5 (n = 2)	1.7 (n = 3)
	Post-operative EN Stay: Sm	14.3 (n = 7)	11.5 (n = 9)	10.6 (n = 8)
	Mm	14.3 (n = 6)	11.3 (n = 4)	11.8 (n = 4)
	Wn	16.0 (n = 2)	9.5 (n = 2)	14.0 (n = 3)
	Total Stay: Sm	18.0 (n = 7)	15.8 (n = 9)	13.7 (n = 8)
	Mm	19.8 (n = 6)	13.3 (n = 4)	14.0 (n = 4)
	Wn	17.5 (n = 2)	11.0 (n = 2)	16.7 (n = 3)

Fig 26 : Impact of Diet on Length of Stay (LOS) (n = 45)



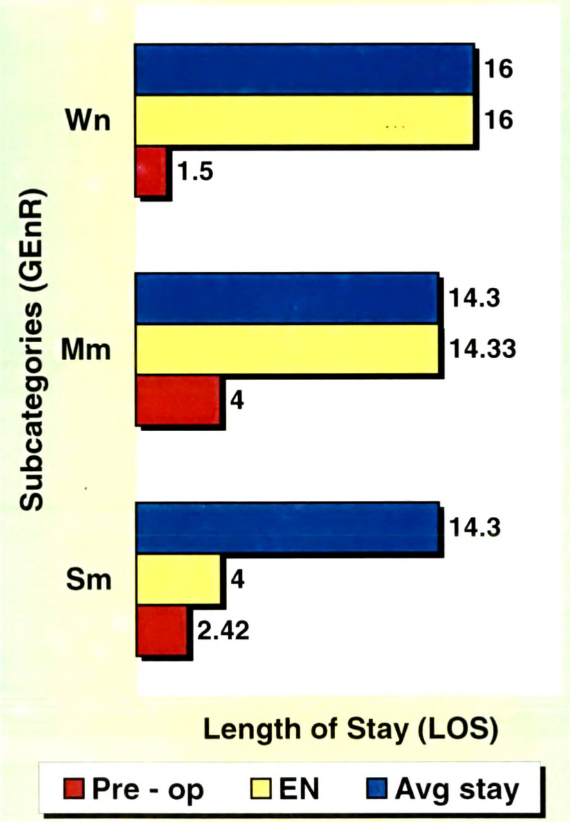


Fig 27 a: Impact of Diet on LOS (GEnR subcategories)

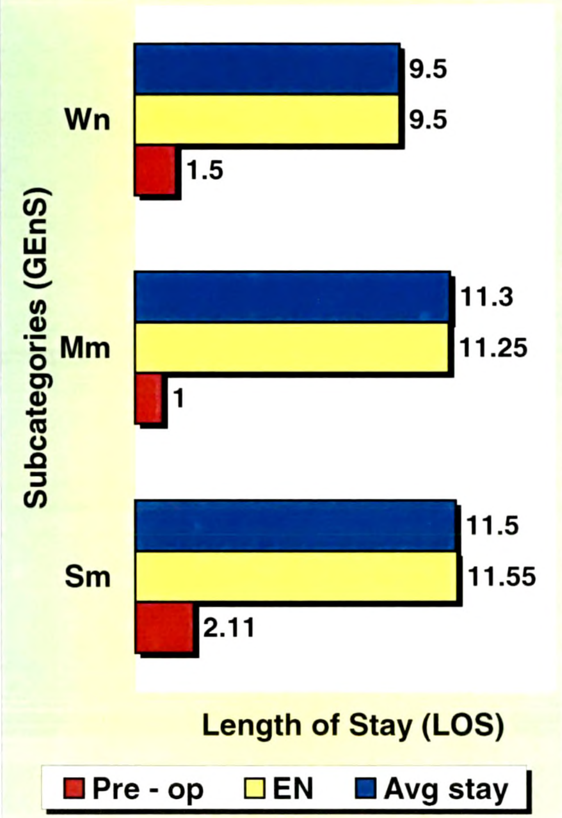


Fig 27 b: Impact of Diet on LOS (GEnS subcategories)

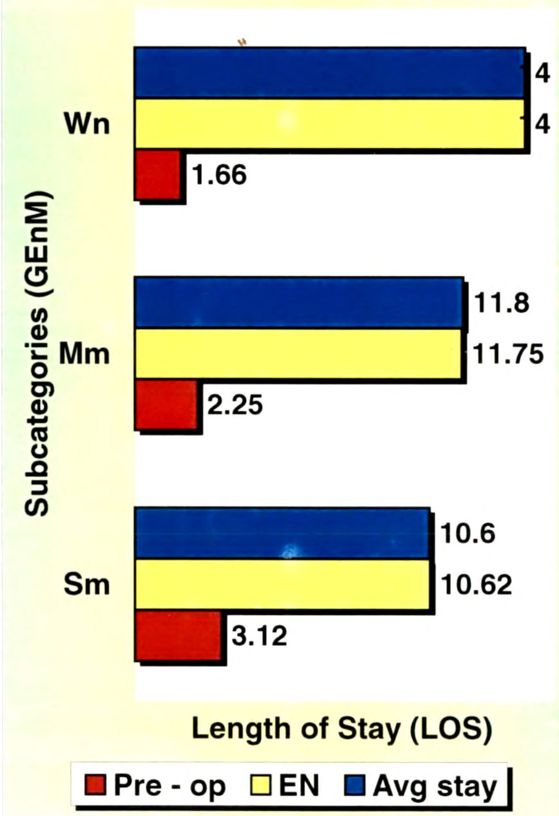


Fig 27 c: Impact of Diet on LOS (GEnM subcategories)

DISCUSSION:

Surgical procedures in general lead to hypercatabolic state. Surgery anesthesia and blood transfusion suppresses immune function and place the surgical patients, risk for post-surgical infectious complications [*Rhoads and Alexander 1995*]. Surgical G.I patients are therefore, at a risk of nutritional depletion due to inadequate surgical stress, subsequent increase in metabolic rate and inadequate nutritional intake A number of malnutrition problems may develop following surgery depending on the surgical procedure and patient's response.

Nutrition has significant impact on a patient's clinical course during hospitalisation affecting all aspects of care from cost of therapeutic intervention and rate of complications to length of hospitalisation and mortality. Optimal nutritional care for a given patient depends in large part on the primary diagnosis and underlying metabolic status. Nutritional therapy should be directed to specific goals depending on patient's nutritional status with immediate goals for nutritional maintenance and ultimate goals in restoration of body mass.

Most recently, nutrition focuses on the changes seen during illness that is a change of 'altered metabolism' seen with organ dysfunction (e.g. renal and hepatic) or patient types (e.g diabetic, critically ill), newer formulas emerged. Since, G.I tract plays an important central role in protein catabolic response after injury, if substrate enriched EN formulas are used for an intended biochemical, physiologic, or clinical outcome, nutrient substrate can be considered pharmacotherapeutic [*Boullata 2002*]. G.I tract serves as a central role as both an endocrine and immune organ. Maintaining adequate barrier function to prevent infection or inflammation requires sufficient perfusion and intact immune function. An immune response initiated at the intestinal mucosa can influence distant sites (respiratory mucosa). This is an impact of 'nutrient gene interactions' is becoming better appreciated [*Sanderson 2000*]. Nutrients may have direct or indirect (*via* neuropeptides, cytokines, eicosanoids, reactive species, cellular adhesion, molecules, growth factors) effects on maintaining the gut microenvironment-perfusion, cellular integrity and immune function. The integrity of the mucosa is dependent on the availability of glutamine, which is used as a substrate for the energy production even in the presence of glucose. Even there are an increasing number of studies showing that glutamine given to catabolic patients produces positive biochemical and clinical effects. Glutamine promotes positive nitrogen balance, preserve muscle mass, enhances immune function and maintains intestinal mucosa integrity and intestinal flora. Thus, any substrate that either dampens the inflammatory response as initiated/perpetuated through the gut or improves gut barrier function has the potential to improve patient outcome; use of such substrate (*e.g* specific aminoacids, fatty acids, micronutrient, growth factors) individually or in combination may prove to be beneficial when the details patient selection, timing and dosing are worked out or in other words its true effect of these formulations are patient specific and nutrient specific. Thus a balanced nutrient intake administration in post-operative stage will reduce negative nitrogen balance thereby promoting a positive effect on the nutritional status. Taking these facts into consideration, the present study was carried out with/ without glutamine to compare the efficacy between protein enriched enteral diets with sources of protein from soy and milk protein and routine hospital diet in gastrointestinal subjects undergoing surgical procedures on overall nutritional status.

STUDY DESIGN:

This present phase of study is based on the *principles of pragmatism.* Pragmatic trials reflect the natural variation that occur between patients and enable measurements of the effectiveness of a treatment and the benefit it produces in routine clinical practice. Such studies also take into account natural variations in individual clinicians preferences. Results are always analysed on *'an intention to treat basis'*. This study was pragmatic in the sense that the attending clinician was allowed to instigate the nutritional support by whatever route he or she considered appropriate or preferable. Patients undergoing surgical procedure related to gastrointestinal problems were recruited. It is our view that nutritional support can be justified to all patients who have sustained or who are anticipated to sustain 7day or more of inadequate oral intake. This is based on the premise that such a period of inadequate intake is associated with deleterious consequences to physiologic functions [*Allison 1992 ; Faubion et.al.,1986*]. This principle obviates to consider preexisting malnutrition or the underlying disease process in the decision to feed. Finally in designing this study attempts are made to keep the homogeneity in the disease type, age group so that valid comparisons of controls and study could be made. Results and discussion in connection to this study have been made for control and study groups and also further focus on the subcategory analysis based on the Nutritional risk Index (NRI) score has been presented. The outcome measures is focused in two aspects - *firstly*, in the relation between the impact of post-operative diet on overall feeding tolerance and *secondly* in terms of improvement in biochemical values, weight loss/gain, overall length of hospital stay.

Discussion has been done in three aspects as per the sections of the results.

Section I:

Recently a number of super-specialty hospitals are coming up in Ahmedabad. Many of them cater to different types of complications efficiently The study was aimed at understanding the inflow pattern and types, particularly gastrointestinal patients, in the ICU's of the three leading hospitals of Ahmedabad. Studies conducted over 1002 patients showed that the male patients in general doubled the number of female patients. Modern lifestyle pattern carries the risk factor of many diseases especially cardiac diseases. In this study exclusively 367 patients were found in hospitals B and C sharing 9.2 % and 90.7 % of the total. Cardiac associated diseases constituted 10.9 % of the total among three hospitals. Numbers of G.I. diseases were found 130 (63.7 %), 47 (23.0 %) and 27 (13.2 %) patients in the A, Band C hospitals sharing 20.3 % of the total. Thus hospital A had more number of G.I cases compared to hospitals B and C.

Length of stay in the hospital was 1 - 7 days for 84.4 % followed by 11.2 % who stayed 8-14 days followed by 4.3 % who stayed for more than 15 days. Longer period of hospital stay was necessary due to the complex nature of disease, which of course, increased the hospital cost undesirably. Mortality of the patients was found to be quite low (3.3 %); picture in the individual hospitals were 6.9 %, 1.6 % and 4.6 % in A, B and C hospitals, respectively. About 94.1 % patients died within 1 - 7 days while 5.8 % patient died in next 7 days. Mortality rate may be explained on the basis of patients' virulent nature of disease, delayed reporting by the patients and patients' physiologic non-response to medical treatment in spite of availability of modern medical technology in the hospitals.

The study brought out the fact that among 1002 ICU patients that G.I. diseases were the second most important one next to cardiac diseases with patients suffering from 41 different gastrointestinal complications.

Section II:

Demography:

Gastrointestinal patients (*n = 61*) needing surgical procedures were allocated randomly to receive enteral diet enriched with protein sources either from soy (*EnS*) (study group 2) or milk (*EnM*) (study group 3) or routine hospital diet (*EnR*) (control group) as per the predetermined protocol. The demographic profile and diagnosis for the three study groups (n = 61); *EnR, EnS, EnM*] were similar in respect to age [range 17-65 years]. Further, types of diseases for each group of patients suffered from, were also found to be almost similar. *EnR* study group composed of patients with mostly acute pancreatitis, fecal fistulas, ulcerative colitis; *EnS* study group had patients with oesophageal stricture, acute pancreatitis, adenocarcinoma of pancreas and *EnM* study group had patients predominantly patients with Ca-oesophagus, oesophageal stricture, duodenal perforation and acute pancreatitis. In general, males were found to double the females in each group for the diseases they suffered. Disease distribution pattern divided 67.2 % patients as upper G.I diseases, 13.1 % patients as lower G.I diseases and 19.7 % patients as miscellaneous. Thus patients suffered more from upper diseases in the three study groups. Here patients with all categories of diseases were more at risk for nutritional depletion as per diseased condition and they further needed to undergo surgical procedures. Surgery injury itself increases resting energy expenditure and protein loss and even intake of energy and protein after gastrointestinal surgical procedures fall well below the requirement during stay in the hospital stay [*Silk and Gow 2001*] thus, nutrition deprivation in patients who have elective gastrointestinal surgical procedures is a normal practice [*Reiland 2000*]. In most of the cases, it is found that *medical and* *surgical problems are accompanied by decline in nutritional status due to changes in intake, metabolism and excretion of nutrition. By the time patients are admitted to hospital, nearly 40 % are 'malnourished' in anthropometric terms (8 % severely) and their nutritional status declines further during their hospital stay [McWhriter and Pennington 1994].* These individuals need to be identified. In this study, the controls (*EnR*) with its subsequent study groups (*EnS* and *EnM*) patients on study entry were on an average found 58.9 % to be 'severely malnourished' (Sm) according to NRI, with almost more than half (57.0 %) of the patients were found to lose 10 % or more than UBW on hospital admission. These are higher proportions than in most other studies. For example, in the Veterans' Affairs (VA) [*1991*] study less than 10 % of the randomised patients were 'severely malnourished' according to NRI. Jeejeboy [*1998*], have documented that weight loss of 5 % over a month or 10 % over any period of time should alert the physician that the patient is malnourished. However, in this case our findings matches with the findings by the study reported by McWhriter and Pennington [*1994*].

Measurements of visceral and somatic protein status are biochemical indices used to evaluate nutritional status. Visceral proteins parameters include albumin, transferin and pre-albumin. According to Charney [*1995*], serum albumin is perhaps the most studied biochemical parameter used in nutritional screening'. Among plasma proteins, albumin is time-tested marker of malnutrition. Albumin is an osmotic protein that constitutes 40 % of the total body protein pool of 4.5 g kg^{-1} and is maintained level of below 3 g dl^{-1} signify malnutrition [*Jeejeboy, 1998*]. Value of < 2.5 g dl^{-1} are associated with increased rate of morbidity and mortality [*Charney 1995*]. The control (*EnR*), and study groups (*EnS, EnM*) had an average serum albumin 2.77 gdl^{-1}, 3.00 g dl^{-1}, 2.97 g dl^{-1}, respectively. In this study, none of the groups had serum albumin < 2.5 g dl^{-1}. Thus, *none of the subjects were at risk level for morbidity and mortality.*

The patient's post-operative course and quality of life are often determined by an adequate preoperative nutritional status assessment and optimised surgical managements. In most of the cases, it is found that medical and surgical problems are accompanied by decline in nutritional status due to changes in intake, metabolism and excretion of nutrition. In general 'well nourished' elective surgical patients are not considered in need of nutritional support, unless post-operative complications prevent oral intake [*Souba 1996*]. Here we have included patients of all categories as per NRI. Evidence to support pre-operative nutrition support is limited but suggests that if malnourished individuals are adequately fed for at least 7 – 10 days pre-operative then surgical outcomes can be improved [*Veterans Affairs Total Parenteral Nutrition Cooperative Study group,1991*]. Pre-operative nutrition enhances wound healing, functional recovery and reduces length of hospital stay [*Chang 2002*]. Average day of pre-operative stay of overall 3 study groups were less than 7days. One reason may be to avoid the increased length of hospital stay for nutritional support and delay in surgical intervention. Studies show a strong correlation between pre-operative malnutrition and post-operative complications as well as mortality after major abdominal surgery [*Townsend 2002 ; Ashley et. al., 2000*]. However, pre-operative diet was based on their on their own diet during pre-operative stage and not the diet as per the study protocol. The study protocol diet was given only during post-operative stage of nutrition. Average pre-operative duration of feeding was 4.0 days, 3.0 days and 2.6 days for *EnR, EnS, EnM* study group, respectively.

Nutrient Intake:

Surgery injury itself increases resting energy expenditure and protein loss and even intake of energy and protein after gastrointestinal surgical procedures fall well below the requirement during stay in the hospital [*Silk and Gow 2001].* Enteral tube feeding (ETF) is only likely to benefit nutritionally depleted patients and those at risk for becoming depleted. Post-surgically ETF is being used in increasing frequency especially oral in take is limited or not possible. It can be administered through nasogastric tube or via post-pyloric nasogastric (NJ) tube or surgical jejunostomy placed pre, inter or post-operatively [*Mshroud 2003*]. It also appears to be beneficial in patients with pancreatitis, although it may need to be avoided in cases complicated by fistulation or pseudocyst formation [*Dejong 2001*] wherein other modified procedures of ETF can be used. In this study, subjects have been administered nutritional support decided by the attending experienced clinician by whatever route he or she considered appropriate or preferable. Supplementation with the formula in this study was done in post-operative stage only. *Pre-operative nutrient intakes in general for the study groups (EnR, EnS, EnM) were found to be less as compared to their requirements*. Energy and protein intake were significantly lower in all the three study groups ($p < 0.05$). Further, subgroup analysis also showed a lower intake in energy and protein by the subcategories in the respective, three study groups. Post-operative nutrient intake by the *EnR* study group during post-operative EN stage reflected a significantly lower intake compared to their requirements ($p < 0.05$), whereas *EnS* and *EnM* study groups had better intake compared to their requirements. However, energy and protein intakes were observed significantly lower in *EnR* study group ($p < 0.05$) whereas, *EnS* study group had better intake of energy and protein intake as compared to their requirements. *EnM* study group had adequate intake of energy but protein intake was found to be significantly lower as compared to their requirements ($p < 0.05$). Further subgroup analysis showed a significant lower intake of energy and protein by three subcategories of *EnR* study group ($p < 0.01$). Sm and Mm subcategories of *EnS* study group had better intake of energy and protein, whereas Wn subcategory had low intake of energy and protein intake was adequate as compared to their requirement. Sm subcategory of *EnM* study group had significantly low intake of energy whereas, calorie intake was found to be adequate for Mm and Wn subcategories as compared to their requirements. However, in all the three subcategories protein intake was found to be significantly low as compared to their requirements ($p < 0.05$). Many other authors have highlighted problems with achieving target intakes with EN [*Woodcock et. al., 2001*]. Inadequate intake in the *EnR* study group were mostly due to insufficient supply and feeding related complications. Moreover, comparison among the Sm subcategories between the three study groups (*EnR, ENS, EnM*) showed that Sm subcategory of *EnS* and *EnM* at post-operative stage had significantly better intake of protein ($p < 0.05$) compared to Sm subcategory of EnR.

Comparison between pre-operative and post-operative intake revealed that energy intake by *EnS* and *EnM* study groups were much better in post-operative EN stage as compared to pre-operative stage. Protein intake was found to be significantly higher in post-operative EN stage in EnS and EnM study groups ($p < 0.05$). Protein intake was found to be better in Sm and Mm subcategories of *EnS* and all three subcategories of *EnM* study groups respectively, on subgroup analysis. Such an observation was not observed in *EnR* study group. *Comparison in adequacies of post-operative intake among groups* further, reflected *that energy and protein intakes were significantly higher in EnS and EnM study groups compared to EnR study group ($p < 0.05$)* [Mann Whitney U-test or Wilcoxon test]. *However, protein intake in Sm* *subcategory was found significantly higher in EnS and EnM study group compared to Sm subcategory of EnR study group. Such an observation was not found in subgroup analysis for EnR study group. Such an observation was not found in subgroup analysis for any of the three study groups (EnR, EnS, ENM*). Moreover, patients receiving EN did not routinely receive prokinetics agents and invasive methods of access were only employed once successful nasogastric feeding had been established moreover some patients were put to nasojejunum (NJ) feeding and feeding jejunostomy (FJ) feeding routes during post-operative support. Thus overall it clearly indicates that *EnR* had a deficit intake of optimal nutrition during pre-operative and post-operative stages compared to actual requirements and compared to *EnS* and *EnM* study groups.

Outcome measures:

a. Complications:

Post-surgical complications in general include feed related complications, infection burden thus slowing recovery and thereby extending hospital stays and increasing hospital expenses The benefits of post-operative feeding in normally nourished surgical patient indicates that it is reduced nutritional intake that predisposes patients to developing complications, including deficits in muscle function and surgical fatigue. There is no evidence that early post-operative enteral feeding should be restricted to malnourished patients undergoing gastrointestinal resection. Indeed one study has found that supplementing 'normal' oral diet in hospital wards as little as 1250(kJ) (300 Kcal) and 12 g of protein/day resulted in reduction of post-op complications in patients undergoing gastrointestinal surgery [*Keele et. al., 1997*]. Feed related complications are predominantly related to symptoms of gastrointestinal intolerance such as large volume of aspirates, vomiting, abdominal bloating and diarrhoea. These complications are in general common reasons for reducing rate or stopping feeds and they are also quite labor intensive in terms of nursing care. In this study complications were mainly related to feeding (EN) and were < 80 % for *EnR* study group even though the diet intake was not significantly satisfactory. The incidence of feed related complications was higher in the enteral fed patients of *EnR* compared to patients of *EnM* and *EnS*. *EnM* had complaints of abdominal distension and diarrhoea but with lesser frequency whereas *EnS* group had very few complaints of abdominal distension, which were corrected accordingly.

Feeding related complications such as abdominal discomfort and diarrhoea are frequently documented in many studies even with patients who are critically ill. The prospective study by Jones *et al.,* [1989] observed abdominal discomfort in 85 % of critically ill patients. Further, a met-analysis by Moore *et. al.,* [1992] reported incidences of abdominal distension and diarrhoea of 46 % and 34 % respectively. One study reported as 80 % incidence of diarrhoea in critically ill patients receiving EN [*Cerra 1988*]. The frequency of diarrhoea has been shown to be inversely related to serum albumin [*Woods and Kelly 1993*], which is often low in critically ill patients as consequence of hepatic reprioritisation of protein synthesis and increased endothelial permeability. This suggests that it may be the oncotic pressure between plasma and bowel lumen [*Woods and Kelly 1993*] or intestinal mucosal edema [*Koretz 1995*] causing diarrhoea. ETF commonly causes gastrointestinal symptoms. Nausea occurs 10 - 20 % of patients [*Jones et. al, 1983*] and abdominal bloating and cramps from delayed gastric emptying are also common [*Duncan et. al., 2001*]. In our study, nausea was 14 % for patients on *EnS* and 10 % for *EnS* whereas, 30 % for *EnR*. ETF related diarrhoea occurs up to 30 % of enteral fed patients in medical or surgical wards and more than 60 % of the patients on ICU [*Benya et al., 1991*]. Incidences of diarrhoea were 5 % for *EnS*, 51 % for *EnR*, 35 % for *EnM*. Abdominal discomfort was common for patients on *EnR, EnM* but less for *EnS*. This was different from Carr *et.al.,* [*1996*] who demonstrated less distention and diarrhoea in their enteraly fed group. Carr *et. al.,* [*1996*] again demonstrated that the incidence of nausea and vomiting was much higher in the enteraly fed patients as compared to the control group. In contrast, the incidence nausea and vomiting was only marginally increased in the enteral fed patients in the study carried out by Heslin *et. al.,*[*1997*] This finding matches with our study group supplemented with *EnM*. However, the difference in the route of feeding, nasojejunal *vs* feeding jejunostomy could be the reason for this difference.

b. Biochemical profile:

Previously controlled trials have shown little improvement in outcome for enteral feeding [*Veterans Affairs Total Parenteral Nutrition Cooperative Study group 1991; Sandstrom 1993*] but these studied patients with normal body composition or mild malnutrition undergoing major elective operation who may differ from the patients reported here. In general well-nourished elective surgical patients are not considered to need nutritional support, unless post-operative complications prevent oral intake [*Souba 1996*]. In this study since disease conditions necessitated to depend solely on enteral nutrition sine oral intake was not possible, thus 'severely malnourished', 'mild moderately malnourished' including well nourished were included in the feeding regime. The impacts of the diets were not equally effective (H - test). *The hemoglobin level did not alter much in all the three study groups. EnR showed a negligible drop in total protein in post-operative stage whereas, a trend for improvement was seen in EnS and EnM study groups. Even EnS and EnM study groups showed an improvement in the albumin level after post-operative EN as compared to pre-operative stage, whereas EnR study group showed a negligible drop in albumin level.* Further, in subgroup analysis, all the three subcategories showed an improvement. In case of EnS study group, Sm subcategory showed an upward trend, whereas Mm and Wn showed downward trend in hemoglobin level during post-operative EN compared to pre-operative stage. Total protein levels of the three subcategories of *EnR* study group showed a downward trend whereas, an upward trend was observed in Sm and Mm subcategory of *EnS* study group and Sm subcategory of *EnM* study group. The albumin level of only Sm subcategory of *EnR* study group showed an improvement whereas, incase of *EnS* and *EnM* study groups Sm and Mm subcategories in EnS and Mm subcategory in *EnM* respectively, showed improvement in post-operative stage. *Thus Sm subcategory in general for the three study groups in general, showed improvement in total protein and albumin levels.*

Moreover, comparison among groups *showed a significant improvement ($p < 0.05$) in total protein and albumin in EnS and EnM study groups* [Mann Whitney U - test or Wilcoxon test]. Further, Sm subcategory of EnS study group had significant ($p < 0.05$) improvement in total protein compared to subcategory of *EnR* study group. Further, a significant improvement in total protein was noticed in Sm subcategory of *EnS* study group ($p < 0.05$) compared to Sm subcategory in *EnR* study group.

c. Weight gain/loss:

Post-operative weight loss (a mean of 1.8 kg in patients receiving intravenous fluids in this study) is acceptable because short-term under nutrition (10 -12 days) do not complicate convalescence after major surgery [*Sandstorm et. al.,1993*]. *Overall, a mean weight loss of 8.66 % was observed for EnR study group, whereas a weight gain of 3.98 % could be observed for EnS study group whereas, a weight loss of only 2.92 % could be noted for EnM study group.* This almost matches with the study reported by Malhotra *et. al.,* [*2004*] where an average weight loss was between the first and 10[th] day was 3.10kg in the study group as compared to 5.10kg in the conventionally managed group. Further analysis indicated that all the three subcategories in *EnR* and study groups had significant weight loss [(Sm : 7.26 %, $p < 0.05$), (Mm: 11.42 %, $p < 0.001$), (Wn: 9.29 %, $p < 0.05$)]. Mm (5.13 %), Wn (3.31 %) subcategories had significant weight loss in *EnM* study group ($p < 0.001$) whereas, weight gain was 5.33 %, 2.77 %, and 1.52 % in the three subcategories respectively, in *EnS* study group. However, a weight gain of 2.21 % only in Sm subcategory was noticed in *EnM* study group. Probably *EnS* and *EnM* study groups had added benefit of optimal nutrition intake along with glutamine.

d. Length of Stay:

Recent studies focus that incidences of length of hospital stay in the ICU and hospital were significantly decreased with the provision of specialised nutrition support [*Wyncoll and Beale, 2001*]. Here an effort has been to provide protein from good biological sources *i.e* kitchen based protein rich polymeric enteral diets with protein sources from soy and milk. As average total stay up to *EN stage was longer for EnR (22.4 days) whereas EnS had shorter stay by 5.9 days; a significant difference was observed with EN stay for EnR compared to EnS and EnM* ($p < 0.05$).

Further analysis showed that Sm subcategory for *EnR* study group had shorter stay whereas Wn of *EnS* study groups and Sm, Wn subcategories in *EnM* study groups had shorter stay. A significant difference could be noted in total length of stay of *EnR* group ($p < 0.05$) compared to *EnM* and *EnS* study group. Moreover, Wn subcategory in *EnR* study group had significantly longer stay compared to subcategories of *EnS* and *EnM* study groups. This results also matches with the observation Weitzelberg *et. al.,* [*2006*] where a significant reductions in infectious complications and LOS in hospital were observed in all groups independent of whether immunomodulation specialised nutrition support was given pre, peri or post-operatively.

Our findings clearly revealed that in general out of three post-operative En diets administered soy enriched followed by milk protein enriched enteral diets were better tolerated by the 'severely malnourished' subjects had a trend for improvement in the biochemical parameters with lesser weight loss and reduction in hospital stay [*Choudhury et. al., 2006*].

e. Cost:

Scientific studies document the relation between good nutrition and good health. During any diseased condition with good nutrition it might help to speed up recovery and so reduce death rate among those who have the chances to survive during any severe illness. Any nutritional intervention done in planned way is always an added advantage. It will have additional positive effect on the effective use of intensive care facility (if the patient is posted in such cases) and hospital costs. However, a cost is often quoted as reason for sub-optimal nutrition support. Through careful analysis one sees that the patients need to stay longer time in hospital. Most of the time patients are not given optimal preoperative nutrition support even. This prolongs healing time and adds to infectious a complication that adds up to the cost of antibiotic therapy the patient is put into as a treatment and prophylaxis. Even parenteral nutrition (PN) is used when EN can be possible. If such factors are considered it is an added cost, which is due to neglect nutrition support. Enteral nutrition formulas usually proteins are costly. *In this present study our formula cost less than Rs: 20.00 p as compared to standard commercial formulas costing more than Rs: 100.00 p per 200 g for enteral formula and more than Rs: 500.00 p per 50 ml of TPN formula.* Thus, a reduction in cost of nutrition intervention could be seen.

Moreover our findings with formula supplemented with *EnS* and *EnM* have also shown reductions in hospital stay compared to controls. Moreover, a reduction in hospital stay has economic implications, like patient will be saved from paying room charges. This is added advantage for the populations of lower socioeconomic group to have better recovery chances through better nutritional care at a lower hospital cost.

Section III:

Demography:

Gastrointestinal patients (*n=45*) needing surgical procedures were allocated randomly to receive enteral diet with protein sources either from soy (G*EnS*) (study group-5) or milk (G*EnM*) (study group-6) or routine hospital diet (G*EnR*) (control group-4) *with substrate enriched glutamine* as per the predetermined protocol. The demographic profile for the three groups: *GEnR, GEnS, GEnM* on an average were similar in respect to age (range: 21 – 70 years) and the types of diseases they suffered from were also found to be similar. Overall G.I disease distributions were 64.44 %, 8.89 % as upper and lower G.I diseases and 26.67 % as miscellaneous group. Thus patients suffered mostly from upper diseases in all the study groups (*GEnR, GEnS, GEnM*). Diseases predominantly for the respective groups were Ca-oesophagus, duodenal malignancy, acute pancreatitis, adenocarcinoma Ca-colon etc. Males were found to suffer double the females in each group. Here patients with all categories of diseases were more at risk for nutritional depletion as per diseased condition and they further needed to undergo surgical procedures. Surgical procedures in general lead to hypercatabolic state [*Jones,1998*]. They have diminished nitrogen economy and require more protein. Severe surgical illness even results in metabolic responses that mobilise substrate (amino acids and fatty acids) from body stores to support vital organs, enhance resistance to infection, and ensure wound healing. Central to this process is the redistribution of body protein, which moves from skeletal muscle to support the central viscera. If unsupported, this protein-wasting state could result in prolonged convalescence diminished immunity and poor wound healing [*Wilmore, 2000*]. Thus a balanced nutrient intake administered in post-operative stage will reduce brief negative nitrogen balance promoting a positive effect on the nutritional status. ETF is preferred whenever patients have adequate accessible gastrointestinal absorptive capacity, as it is both more physiological and cheaper.

Despite improvements made in post-surgical care, infectious complications continue to be a major problem. Analysis of surveillance data on approximately 499,000 patients collected between 1992 and 1998 from 205 medical-surgical ICUs showed a 14 % incidence of surgical site infections. In a study of 255 pairs of patients with and without surgical site infections, patients with infections were twice as likely to die, 60 % more likely to spend time in the ICU, and 5 times more likely to be readmitted to the hospital. Up to 50 % of surgical patients are malnourished before or become malnourished following surgery [*Novartis Medical Nutrition 2006*]. These individuals need to be identified. A weight loss of more than five percent in one month or of 10 % or more in six months, a serum albumin of less than 3.2 g dl^{-1} and total lymphocyte of less than 3.000 / mm^3 can signify increased risk of post-op complications [*Megiud et.al.,1990; Leiti 1987*]. In this study, control patients (*GEnR*) and their subsequent study group patients (*GEnS and GEnM*) were on an average identified 53.3 % as 'severely malnourished' according to NRI score with 35.6 % patients were found to lose 10 % or more than UBW on study entry. This is opposite to the results reported in the *Veterans Affairs Total Parenteral Nutrition Cooperative Study group* [*1991*] study where less than 10 % of the randomised patients were severely malnourished according to NRI.

Albumin is commonly thought as a good indicator of nutritional status and visceral proteins [*Sungurterkin 2004*]. The NRI is derived from the serum albumin concentration and the ratio of actual to usual weight with the equation. This index was used in Veterans Administration Cooperative Study that evaluated the effect of perioperative nutritional support [*1991*]. The controls (EnR), and study groups (EnS, EnM) had average serum albumin 2.66 g dl^{-1}, 2.85 g dl^{-1}, 3.04 g dl^{-1}, respectively. In this study, *none of the groups had serum albumin < 2.5 g dl^{-1}. Thus, none of the subjects were at risk level for morbidity and mortality.*

Nutrient Intake:

Perioperative nutritional intervention may improve the patient's metabolic responses to a gastrointestinal surgical procedures and his or hers long term sequelae. Even it is stated that subjects undergoing elective major procedures, pre-operative of IED for 5 - 7 days before elective surgery appears to improve clinical outcome [*Woodcock et. al., 2001*]. Studies also demonstrate that patients who should receive early enteral nutrition with IED (immunoenhancing diet) are malnourished elective G.I surgical patients (albumin < 3.5 g dl^{-1} for upper G.I tract and 2.8 g dl^{-1} for lower G.I tract [*Eastern association 2003*]. Thus these above reports matches with our study and the enrolled patients can be considered as candidates for receiving IED.

Studies have shown that patients receiving pre-operative enteral nutrition had 20-60% fewer major post-operative complications when compared with control group receiving standard oral diet [*Chang 2002]*. Marco *et al.,* [*2002]* reported that malnourished subjects (weight loss > 10 %)candidates for major elective surgery for the malignancy of GI had lesser post-operative complications and significant shorter post-op days compared to the control group when supplemented with IED. In 3 studies [*Waitzberg et. al., 2006*] treatment was exclusive pre-operative and Immunonutrition was compared with standard formula that was isonitrogenous and isocaloric. Even studies describe the health economic advantage of specialised nutrition for 5 days prior to surgery in CI patients. [*Braga et. al.,* 2005]. Once stated an IED should be aggressively administered with the goal of providing at least 50 – 60 % of the patients calculated daily requirement goal and continued for at least 5 days with subsequent reevaluation [*Proceedings from the summit 2001*]. However, in this study we could not provide the enrolled subjects with IED during pre-operative nutrition stage as a part of support as longer pre-operative stay adds total health care cost of treatment and moreover patients were unwilling for longer pre-operative stay. The pre-operative diet was based on their own diet during pre-operative stay and not the diet as per the study protocol which was given only during post-operative nutrition stage. Average pre-operative feeding during hospital stay was 2.9 days, 1.7 days and 2.6 days for *GEnR, GEnS* and *GEnM,* respectively. Pre-operative nutrient intake *in general for the study groups (GEnR, GEnS, GEnM) were adequate compared to their requirements; energy intake by the respective three groups were adequate, but protein intake was found to be low which is statistically significant (p < 0.05) as compared to their requirements*. Further, during pre-operative stage, Sm and Mm subcategories had significantly low intake of protein ($p < 0.05$), whereas significantly low intakes of energy were noted for Mm subcategory compared to their requirements a downward trend of protein intake was observed in Wn subcategory as compared to their requirements. The subcategories of *GEnS* study groups had adequate intake of energy, but significantly a low intake of protein was noted by Sm and Mm subcategories ($p < 0.05$). The energy and carbohydrate intakes were adequate in three subcategories in *GEnM* study groups compared to their requirement. The protein intake was found to be lower in all the patients and was significantly lower in Mm subcategory ($p < 0.05$) in *GEnM* study group.

During *post-operative EN stage* the energy and protein intake by *GEnR* study group was significantly lower ($p < 0.05$) as compared to their requirement. A better intake was noted in *GEnS* and *GEnM* study groups as compared to their requirements. All the three subcategories, Sm, Mm, Wn in *GEnR* had low intakes of energy and protein as compared to their requirements. Sm and Mm categories had adequate intake of energy in *GEnS* study group. Protein intake was significantly low in Mm subcategory whereas, Wn subcategory had low intake of protein and fat as compared to their requirement. In case of *GEnM* study group, the energy and protein intake in Sm, Mm and Wn were found to be adequate as compared to their requirements.
The energy intake of GEnR study group was significantly low in post-operative EN stage as compared to pre-operative stage ($p < 0.05$). *Energy intake was better in GEnS whereas low in GEnM study group in post-operative EN as compared to the pre-operative stage.* However, *protein intake was found to be higher in GEnS study group and GEnM study groups as compared to pre-operative stage.* Further with subgroup analysis it was observed that the protein intake was significantly higher in Sm, Mm subcategories belonging to *GEnS* study group and Mm subcategory of *GEnM whereas in* control group (*GEnR*) there was no appreciable increase in protein intake. *Comparison in adequacies of post-operative intake among groups* further reflected *that energy and protein intakes were significantly higher in GEnS and GEnM study groups compared to GEnR study group ($p < 0.05$)* [*Mann Whitney U-test or Wilcoxon test*]. *However, protein intake in Sm subcategory was found significantly higher only in GEnM study group compared to Sm subcategory of GEnR study group. Such an observation was not found in subgroup analysis for the other two study groups* (*GEnR, GEnS*). Thus, *GEnR* group had overall low intake in energy and protein compared to *GEnS* and *GEnM* study groups. Moreover, controls and study subjects receiving kitchen based polymeric protein rich EN diets with substrate enriched with glutamine did not routinely receive prokinetics agents and invasive methods of access were only employed once successful nasogastric feeding had been established moreover some patients were put to NJ feeding and FJ feeding routes during post-operative support.

Outcome measures:

We have tried to focus the relation between the impact of post-operative diet in overall feeding tolerance and also in terms of improvement in biochemical values, weigh loss/gain and its impact on length of hospital stay and there cost of stay.

a. Complications:

Studies show that compared with surgical patients fed a standard high nitrogen formula, patients fed on formula supplement with immunonutrients had quicker return of immune function to pre-operative levels, significantly fewer infectious complications and shorter hospital stay [*Norvartis Medical Nutrition 2006*] whereas reduced nutritional intake even for normally nourished may even predispose to post-operative complications. Post-surgical complications in general include feed related complications, infection burden thus slowing recovery and thereby extending hospital stays and increasing hospital expenses. Thus early nutrition is safe and is associated with beneficial effects such as lower weight loss, early achievement of nitrogen balance compared to conventional feeding practices [*Malhotra et.al., 2004*]. Moreover a recent meta-analysis of 14 randomised trials evaluating human enteral glutamine therapy demonstrated fewer infectious complications and shorter hospital stay of almost 3 days [*Novak 2002*] In this present study average post calorie EN intake on an average even ranged nearing 75 % (*GEnR*) but serious complications were not noted.

In general patients on enteral feeding schedule have complications predominantly related to symptoms of G.I intolerance such as large volume of aspirates, vomiting, abdominal bloating and diarrhoea. These complications are in general common reasons for reducing rate or stopping feeds and they are also quite labor intensive in terms of nursing care [*Jones et. al., 1983*]. In this study the incidence of feed related complications was higher in the enteral fed patients of *GEnR* compared to patients of *GEnM* and *GEnS* study groups. Feed related complications in *GEnR* study group was more in all three subcategories compared to *GEnS* and *GEnM* study groups. *GEnR* study group had complaints of abdominal distention and diarrhoea; *GEnM* study group had complaints of nausea more compared to *GEnS* study group whereas, *GEnS* group had very few complaints of abdominal distension, diarrhoea that were corrected accordingly. It should be noted here that none of the groups had diarrhoea more than 2 times. Thus this may be termed as loose stools instead of diarrhoea. Moore [*1992*]. Meta - analysis reported incidences of abdominal distension and diarrhoea of 46 % and 34 % respectively. One study reported as 80 % incidence of diarrhoea in CI pts receiving EN. ETF commonly causing gastrointestinal symptoms of nausea occurs 10 - 20 % of patients [*Jones et.al., 1989*] and abdominal bloating and cramps from delayed gastric emptying are also common [*Duncan and Silk 2001*]. This finding does not match with our results. In our study, nausea was 40 % for patients on *EnS* and 60 % for *GEnM* whereas, 46.6 % for *EnR*. ETF related diarrhoea occurs up to 30 % of enteral fed patients in medical or surgical wards and more than 60% of the patients on ICU [*Benya et al., 1991*]. Incidences of diarrhoea were 26.7% for *EnS*, 53.3 % for *EnR*, 40.0 % for *GEnM*. Abdominal discomfort was common for patients *on EnR, EnM* but less for *EnS*. Heslin *et al.*, [*1997*] reported that the incidence nausea and vomiting was only marginally increased in the enterally fed patients. This finding matches with our study group supplemented with *EnM*. However, the difference in the route of feeding, nasojejunal *vs* feeding jejunostomy could be the reason for this difference.

b. Biochemical profile:

During catabolic states like major surgery or inflammation, gut barrier could be altered. It has been reported that pre-operative nutritional support may have beneficial effects on clinical outcome in patients with surgery on G.I tract. Glutamine, a conditionally essential aminoacid reported to modulate protein metabolism in intestine [*Clinical trials.com 2005*]. In general impacts of diet on biochemical parameters were not equally effective in improving total protein and albumin levels. It may be reminded once more that if malnourished individuals are adequately fed for at 7-10days pre-operatively then surgical outcomes can be improved [*Veterans Affairs Total Parenteral Nutrition Cooperative Study group 1991*]. The obvious disadvantage of this is increased length of hospital stay resulting from admission for nutritional support and the delay in surgical intervention. In our study we could not provide pre-operative IED to our patients, one of the reasons being mentioned above.

In general well-nourished elective surgical patients are not considered to need nutritional support, unless post-operative complications prevent oral intake [*Souba 1996*]. In this study phase, since disease conditions necessitated to depend solely on enteral nutrition as oral intake was not possible, thus 'severely malnourished', 'mild moderately malnourished' including well nourished were included in the feeding regime. The impacts of the diets were not equally effective (H - test). *In the post-operative stage, hemoglobin levels did not alter much in all the three study groups except GEnS.* Total protein levels in *GEnS* study group showed improvement whereas, a slight improvement was recorded in *GEnM* study group after post-operative EN stage compared to pre-operative stage. *GEnR* study group however, showed a negligible improvement in total protein. Similarly, improvement in albumin level is observed for *GEnS* whereas, a slight improvement is noted for *GEnM* after post-operative EN as compared to pre-operative stage. On subgroup analysis, it was observed that hemoglobin from the two subcategories (Sm, Mm) showed a drop after EN stage whereas, an upward trend was noted in Wn subcategory of the *GEnR* study group. Total protein level showed a downward trend after EN stage in Sm and Mm subcategories whereas, an upward trend was noted in Wn subcategory. Albumin level in Sm and Wn subcategories showed an upward trend whereas, a downward trend was observed for Mm subcategory. Hemoglobin level of *GEnS* study group showed an upward trend in Sm, Mm and Wn subcategories after EN stage. An upward trend for total protein and albumin was also noted in Sm, Mm and Wn subcategories. The level of hemoglobin level showed a drop in pre-operative stage in all the three subcategories of *GEnM* study group. Total protein and albumin levels of Sm subcategory showed an upward trend whereas, in Mm and Wn subcategories, a downward trend was noticed. Thus we can say that supplementation of glutamine might act as an added benefit in improving protein status. This match to some extend with the study reported by Lin *et. al.,* [*2002*] where their results with gln supplementation showed a tendency to have cumulative nitrogen balance on the post-op days even in patients with low APACHE II scores.

Moreover, *comparison between groups showed a significant improvement ($p < 0.05$) in total protein and albumin levels in GEnS and only total protein level in GEnM study groups* [Mann Whitney U-test or Wilcoxon test]. However such an observation was found in Sm subcategory in *GEnM* study group compared to *GEnR* study group only.

c. Weight gain/loss:

Hover at al., showed that pts who were given early enteral feeding did not demonstrate any weight loss. Since their cases were undergoing elective upper GI surgery, they were not in a state of septiceamia or increased catabolism pre-operatively. These cases could therefore, be fed immediately by jejunostomy tube. But jejunostomy feeding may result in certain complications, which are avoided by our technique. Post-operative weight loss (a mean of 1.8 Kg in patients receiving intravenous fluids in this study) is acceptable because short-term under nutrition (10 – 12 days) do not complicate convalescence after major surgery [*Sandstorm et al., 1993*]. In this study, patients registered loss of weight in *GEnR* study group (1.60 Kg) as compared to the time of admission to the time of discharge ($p < 0.001$) whereas, in case of *GEnS* (2.20 Kg) and *GEnM* (1.36 Kg) study groups, a small increase in weight was observed during discharge, which is statistically significant ($p < 0.05$). Further subgroup analysis, a weight loss was observed in Sm, Mm and Wn subcategories and statistically significant for Sm and Mm subcategories. Out of the three subgroups in *GEnS* study group, the weight gain was statistically significant ($p < 0.05$) in Sm subcategory [3.24 Kg] and Mm 0.30 kg (0.43 %). Wn subcategory also recorded increase in weight [1.35 Kg] at the time of discharge and was found to be statistically non-significant. Of the three subcategories from *GEnM* study group, only Sm (2.08 Kg) and Wn (3.00 Kg) subcategories recorded a statistically significant ($p < 0.05$) small increase in weight whereas Mm subcategory recorded a loss of weight (1.33 Kg) at the time of discharge as compared to the value observed at the time of admission. Probably *GEnM* and *GEnS* had added benefit of overall nutrition intake along with glutamine.

d. Length of Stay:

Braga [*2002*] reported a prospective randomized study reported that malnourished subjects (weight loss ≥10 %) candidates for major elective surgery for the malignancy of G.I had lesser post-op complications and significant shorter post-operative days compared to the control group. Novak [*2002*] also reported in a recent meta-analysis of 14 randomised trials evaluating human enteral glutamine therapy demonstrated fewer infectious complications and shorter hospital stay of almost 3 days. Post-operative enteral feeding was done for 15.0 days, 11.2 days and 11.6 days in *GEnR,* *GEnS* and *GEnM* group, respectively. With respect to total number days, the mean values were 18.7days by *GEnR* study group, 14.5 days in *GEnS* and 14.4 days in *GEnM*, respectively. Powel *et. al.,[1999]* also reported that supplementation of glutamine showed a significant reduction in length of stay in surgical patients. On subgroup analysis, the average stay up to EN stage Sm, Mm, Wn subcategories of *GEnR* study group was 18.0 days, 19.8 days, 17.5 days, whereas the subcategories (Sm, Mm, Wn) of *GEnS* study group had 15.8 days, 13.3 days, 11.0 days average stay up to EN stage. Average stay up to EN stage was 15.8 days, 13.3 days, 11.0 days respectively in *GEnM* study group.

e. Cost:

Studies that have focused upon the specific patient population however, (malnourished G.I surgery) have routinely identified reductions in infectious complications, length of hospital stay, antibiotic days, ventilator days, incidence of MOSF with a trend towards improved survival that would make this therapy cost-effective [*Eastern Association 2003 ; Proceedings from the Summit 2001]*. Nutrition has significant impact on a patient's clinical course during hospitalisation. Nutrition is often a neglected parameter in patient care in most of the surgical suites in most of the hospitals. Many a time in a country like India cost and infrastructural problems make parenteral nutrition a rare commodity. Enteral nutrition therapy is considered a costly affair for lower socioeconomic group. It is often quoted as reason for sub optimal nutrition support. However, on careful analysis ones sees that patient is unnecessarily added load of medication, which would have been easily reduced through peri-operative nutrition with the help of good nutrition support team. Commercial immune enhancing diets are expensive patients are mostly deprived their advantages. Griffiths *[1999]* reported that there was 25 % reduction in the total costs of ICU and 15 % reduction in the total cost of hospital care of all patients receiving glutamine. In our study, we tried to do substrate enrichment with glutamine to the already tried formulas in phase I. The product was less expensive (Rs: 50.00 p 100g $^{-1}$) compared to the immunoenhancing formulas present in the market. Even studies showed a positive effect on the study subjects and had also been able to contribute a shorter stay in the hospitals. This if used carefully in specific conditions will help the patients to save revenues from paying room charges. Thus even patients with lower socioeconomic group can have the advantages of IED.

IMPACT OF GLUTAMINE (WITH / WITHOUT) ENRICHMENT IN OVERALL BIOCHEMICAL OUTCOME OF STUDY PATIENTS

a. Comparison between study groups *(EnR, EnS EnM)* in Overall outcome:

The values in the Table 17 shows that out of the three study groups, in *EnR* study group 43.0 % patients had improvement in total protein level and 52.4 % had improvement in albumin level compared to their values at pre-operative stage whereas, 52.4 % and 43.0 % patients had downward trend in total protein and albumin levels. An upward trend in the above values was observed in *EnS* study group patients (TP: 52.4 % ; Alb: 52.4 %) whereas a lesser percentage of patients had a downward trend in the respective values (TP: 38.1 % ; Alb: 24.0 %). The *EnM* study group also had improvement in total protein (57.1 %) and albumin (57.1 %) whereas a lesser percentage of patients had a downward trend in the respective values (TP: 39.0 %; Alb: 38.1 %). *Thus, in general an improvement total protein and albumin levels were observed higher percent in EnM and EnS group patients respectively among the three study groups* [Table 17] [Fig. 28].

b. Comparison between study groups *(GEnR, GEnS, GEnM)* in Overall Outcome:

In general an overall improvement in both total protein and albumin was recorded in three study groups (*GEnR, GEnS, GEnM*). In case of *GEnR* study group, the levels of total protein and albumin improved in 66.7 % and 73.33 % patients respectively, whereas a downward trend in the values were observed in 33.33 % and 26.7 % patients, respectively, compared to their values at pre-operative stage. A better picture was observed in *GEnS* study group with 93.33 % patients showing an upward trend in total protein and 86.7 % patients in albumin levels as compared to their values at pre-operative stage. However, only 6.7 % and 13.3 % patients had a downward trend in the above values. Moreover, an upward trend in total protein and albumin were observed in 47.6 % and 73.3 % patients respectively, in *GEnM* study group as compared to their values at pre-operative stage. *Thus, in general an improvement total protein and albumin levels were observed higher especially in GEnS study group patients followed by GEnM and GEnR study group patients respectively among the three study groups* [Table 17] [Fig. 28].

c. Impact of with *(GEnR, GEnS GEnM)* (Or) without *(EnR, EnS EnM)* glutamine supplementation between study groups and Comparison among the groups in Overall outcome:

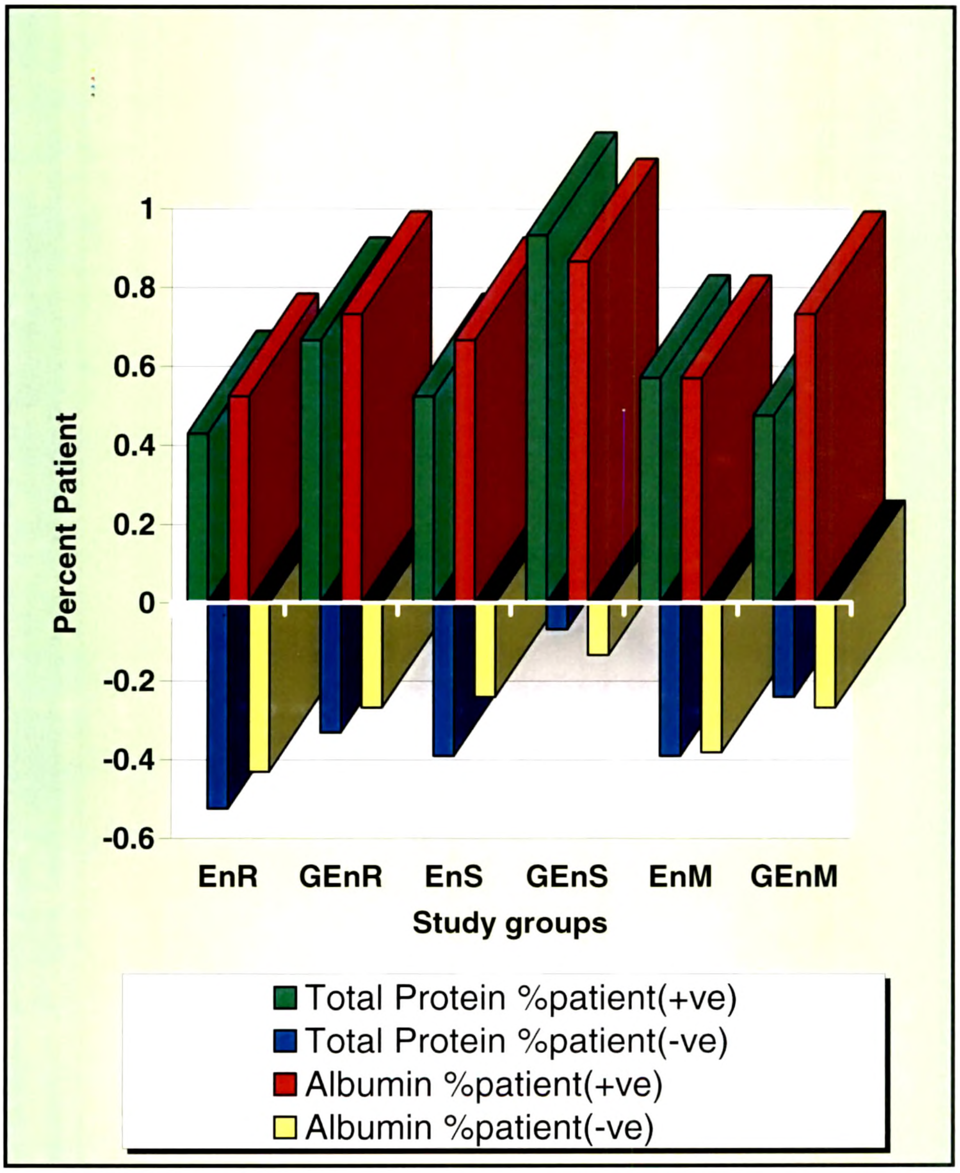
Comparison between study groups with and without glutamine enriched polymeric kitchen based protein enteral diets and controls showed an increase in both total protein and albumin levels in *GEnR* patients compared to *EnR* study group [(TP: 66.7 % vs 43.0 %) (Alb: 73.3 % *vs* 52.4 %)]. Moreover, percentage of patients showing downward trend in the above values were low in *GEnR* compared to *EnR* study group [(TP: 33.33 % vs 52.3 %) (Alb: 26.7 % *vs* 43.0 %)]. An interesting picture was noted both *EnS* and *GEnS* group patients. Though a higher percentage of patients in *EnS* study group had an upward trend in total protein and albumin level but still a much better results were elicitated by patients in *GEnS* group [(TP: 93.33 % *vs* 52.4 %) (Alb: 86.7 % *vs* 66.7 %)]. The lesser percent of patients in *GEnM* group had improvement in total protein levels, whereas 73.3 % patients had upward trend in albumin levels as compared to 54.1 % patients in *EnM* study group. Downward trend in total protein and albumin levels were recorded only with 24.0 % and 26.7 % patients in *EnM* and *GEnM* study group respectively [Table 17] [Fig. 28].

Thus, the present study clearly revealed that out of six post-operative polymeric kitchen based protein rich EN diets to the study groups with sources of protein from soy (*EnS*) followed by milk (*EnM*) was in general better tolerated by the patients and had a trend for improvement in the biochemical parameters with lesser weight loss and reduction in the hospital stay compared to patients on routine hospital enteral diet (*EnR*). Similar observations were noticed with subsequent substrate enrichement with glutamine but in case of *GEnR* study group a slow trend was noticed.

Table 21: Effectiveness of with/without Glutamine Enrichment on Overall Outcome of the Study Groups (n = 61)

	Total Protein (% patients)			**Albumin (% patients)**		
Study groups	No change	Positive trend	Negative trend	No change	Positive trend	Negative trend
EnR	4.8 %	43.0 %	52.4 %	-	52.4 %	43.0 %
GEnR	-	66.7 %	33.3 %	-	73.3 %	26.7 %
EnS	4.8 %	52.4 %	39.0 %	-	66.7 %	24.0 %
GEnS	-	93.3 %	6.66 %	-	86.7 %	13.3 %
EnM	4.8 %	57.14 %	39.0 %	-	57.1 %	38.1 %
GEnM	-	47.6 %	24.0 %	-	73.3 %	26.7 %

Fig 28: Effectiveness of Glutamine Enrichment on the Biochemical Improvement of the Study groups (n = 106)



Further comparisons also indicate that polymeric kitchen based protein rich i.e, soy enteral diet with subsequent substrate enrichment with glutamine (*GEnS*) has a tendency in improving both total protein and albumin levels as compared to respective enteral diets with or without glutamine. Thus improvement in above biochemical values has positive indication for a trend towards improvement in status. This positive effect of both soy based polymeric kitchen based EN diet and subsequent enrichment with glutamine may be explained in the light that glutamine content of soybean is more than whey and casein in milk [*Subulakshmi 2004*] So better results in *EnS* and *GEnS* study groups were exhibited than *EnM* and *GEnM* study groups, respectively. However, this is an observation with limited number of patients and needs further trials, which may serve as a promise in providing future benefit in support to the surgical G.I patients.

Relation between lean body mass and length of stay was also noticed in this study. Both *EnR* and *GEnR* study groups had increase weight loss compared to their requirement and so increased LOS was recorded for the respective groups. This matches with the important study reported by Pichard *et. al.,* [*2004*] that *a decrease in lean body mass is associated with a longer LOS*. The *past is the future*: the study by Pichard *et. al.,* [*2004*] may renew interest in the assessment and improvement of protein mass and protein metabolism in clinical studies because it suggests an association with the clinically relevant endpoint LOS.

Lastly, several criticisms of this study should be addressed. First, the group of patients was very heterogeneous, and it might have been preferable to study patients with one disease in detail. We deliberately studied this heterogeneous population because our aim was to study the relationship between nutritional status and impact of formulas on overall improvement in nutritional status during surgical procedures in surgical gastrointestinal patients. If a statistical correlation could be shown in these study patients, it would have strengthened the need for treatment of malnutrition. However, *EnS* and *GEnS* appears to be beneficial for surgical G.I patients.