Effect of Early Immunonutrient Supplementation after Enteric Anastomosis in the Prevention of Post Operative Complications As Compared To Conventional Approach

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Abstract

This study was conducted to determine whether post-operative immuno nutrition in patients undergoing elective / emergency gastrointestinal anastomosis (malignant or benign disease) could improve clinical outcome.

In the present study, I have done a randomized, prospective comparative study of "EFFECT OF EARLY IMMUNONUTRIENT SUPPLEMENTATION AFTER ENTERIC ANASTOMOSIS IN THE PREVENTION OF POST OPERATIVE COMPLICATIONS AS COMPARED TO CONVENTIONAL APPROACH". In the Department of General Surgery, R G Kar Medical College and Hospital, Kolkata from January 2014 to June 2016.

The rates of infectious complications have decreased especially wound infections, anastomotic leaks decreased, rates of abdominal abscess decreased & the mean length of stay in hospital decreased by 2 days approximately. Though this study does not show any significant difference in the mortality between these two groups still it have proved that supplementing early diet in post operated gastrointestinal surgery patients with immunonutrients.

Key Wards: Immunonutrient, Supplementation, Enteric Anastomosis, Post Operative Complications

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Date of Submission: 25-02-2019 Date of acceptance:11-03-2019

I. Introduction

Major abdominal operations lead to post traumatic deregulation of immune system, which is characterized by suppression of immune functions^{1,2}. The increased susceptibility to infections results from a multitude of metabolic or immunologic imbalances according to trauma, tissue ischemia and surgical injury, length and operation, loss of blood, associated illness and malnutrition. ³ Mucosal lesions and increased intestinal permeability can provoke trans-location of bacteria and endotoxins and initiate immune-inflammatory response and so thus have a high impact on the development of complications by infections. ⁴⁻⁷Enteral nutrition provides the intestinal mucosa with nutrients and maintains the gut associated lymphoid tissue (GALT) which may reduce bacterial trans-location.^{8,9} In many early studies post-operative administration of immune enhancing formulas have shown to improve gut function and positively modulate post-surgicalimmunosuppressive and inflammatory response. ¹⁰⁻¹⁴

Arginine, glutamine, omega-3-fatty acids and ribonucleic acid(RNA) are immunonutrients which can modulate the immune system and improve host defence mechanisms after major surgery. ^{15,16}

Arginine protects against ischemia / reperfusion injury, promotes T cell maturation and activation and improves nitrogen balance ^{6,9}. Glutamine serves as an important energy source for the gut mucosa. Various immunologic cells and other rapidly dividing cells require glutamine for their metabolic processes ^{7,8}. Omega 3 fatty acids have a role in modulating the production of both lipids (eicosanoids) and proteins (cytokines) mediators . They reduce systemic inflammation, minimize hepatic ischemia injury and normalize vascular flow properties ^{6,9}. Nucleotides improve protein synthesis, facilitate intestinal cell maturation , and have a regulatory role in the T cell mediated immune response ^{6,9,17}.

The first clinical study of post-operative immuno nutrition has been done by Daly in 1992. After that Senkel, Braga and Gianotti have studied post, peri and pre-operative immunonutrition in gastrointestinal cancer patients 19-23. In most trials the results have been auspicious and immuno nutrition have been advocated.

This study was conducted to determine whether post-operative immuno nutrition in patients undergoing elective / emergency gastrointestinal anastomosis (malignant or benign disease) could improve clinical outcome.

II. Materials And Methods

STUDY AREA:All elective and emergency 60 (30 in each group)patients had requiring enteric anastomosisat R.G.KAR MEDICAL COLLEGE & HOSPITAL

Inclusion criteria: patients who have undergone enteric anastomosis on an emergency or elective basis **Exclusion criteria**:

- 1) Patient with ASA grade IV to VI
- 2) Re-laparotomies
- 3) Immunosuppressed patient
- 4) Patients with renal failure
- 5) Age less than 12 years
- 6) Pregnant females
- 7) Patients with spinal injury

30 patients (50% of sample size) of enteric anastomosis done by the standard technique of single layer interrupted stitches will be given 30-45 ml of clear water after 6 hours after surgery; and then on wards liquid diet 400 ml/day in the form of tea, fruit juice and immunonutrients enriched powder (containing Glutamine, Arginine & Omega 3 fatty acid) dissolved in water twice-a-day started within 48 hours of surgery. If abdominal distension, nausea or vomiting develops then nasogastric tube suction will be done to decompress the stomach. Amount of liquid diet will be increased gradually and soft diet will be introduced according to response of the patient. Immunonutrients enriched powder dissolved in water twice-a-day will be continued up to 7th post-operative day.

Other 30 patients of the control group will be kept on maintenance intravenous fluids containing dextrose and saline. Nasogastric tube will be removed and feeds will be started orally depending on the clinical condition of the patient and appearance of bowel sounds as is done conventionally.

In this period any adverse effects like anastomotic dehiscence detected early (by features of peritonitis or confirmed radio-logically by leakage of dye intraperitonealy from the anastomotic site) will be managed conservatively by withholding enteral feeding, giving intravenous fluids and antibiotics.

Statistical Analysis:

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS 24.0. and GraphPad Prism version 5. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test where in the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. p-value ≤ 0.05 was considered for statistically significant.

III. Result And Analysis

We found that bar Diagram shows average distribution of age in conventional and immunonutrient group. It was found that mean body weight of both Conventional and immunonutrient group.

We found that in conventional group total males &females were 12 and 18 as compared to 16 & 14 of immunonutrientgroup. P value is statistically insignificant.

It was found that total comorbid patients in conventional group were 8 as compared to 6 of immunonutrient group. P value is 0.5415 which is statistically insignificant.

We found that comparision of Pre-operative serum albumin level in conventional and immunonutrientgroup. Mean value of serum albumin in conventional group is 3.67g/dl as compared to 3.8g/dl of immunonutrientgroup.P value is 0.8444 which is statistically insignificant.

It was found that comparision of Post-operative day 2 serum albumin level in conventional and immunonutrient group . Mean value of serum albumin in conventional group is 3.33g/dl as compared to 3.69g/dl of immunonutrientgroup.P value is 0.0111 which is statistically significant.

We found that comparison of Post-operative day 8 serum albumin level in conventional and immunonutrient group. Mean value of serum albumin in conventional group is 3.38g/dl as compared to 3.76g/dl of immunonutrient group. P value is 0.0059 which is statistically significant.

It was found that total number of Gastric carcinoma patients in conventional group were 5 as compared to 6 of immunonutrient group. P value is 0.7386 which is statistically insignificant.

It was found that total number of colorectal carcinoma patients in conventional group were 7 as compared to 4 of immunonutrient group. P value is 0.3168 which is statistically insignificant.

We found that there were no patients with crohns disease in either of these groups.

It was found that total number of Miscellaneous Benign patients in conventional group were 19 as compared to 20 of immunonutrient group. P value is 0.7866 which is statistically insignificant.

It was found that anastomotic leak was present in 8 patients of conventional group as compared to just 1 of immunonutrient group .P value is 0.0113 which is statistically significant.

We found that surgical wound infection was present in 9 patients of conventional group as compared to 3 patients of immunonutrient group. P value is 0.0528 which is statistically insignificant.

It was found that abdominal abscess was found in 7 patients of the conventional group as compared to 1 patient of immunonutrientgroup. P value is 0.0226 which is statistically significant.

We found that respiratory tract infections were present in 4 patients of conventional group as compared to 2 patients of the immunonutrient group. P value is 0.3894 which is statistically insignificant.

It was found that non-infectious complications were present in 5 patients of conventional group as compared to 2 patients of the immunonutrient group. P value is 0.2276 which is statistically insignificant.

We found that 2 patients of conventional group lost their lives as compared to 1 patient of immunonutrient group during the course of treatment . P value is 0.5536 which is statistically insignificant.

It was found that the mean length of stay in hospital of the conventional group was 9 days as compared to 7 & 1/2 days in the immunonutrient group. P value 0.0043 which is statistically significant.

IV. Discussion

This study compared the post-operative outcome in the two groups, one group was treated conventionally while the other group was given immunonutrient supplementation early postoperatively [30-45 ml of clear water after 6 hours after surgery; and then on wards liquid diet 400 ml/day in the form of tea, fruit juice and immunonutrients enriched powder(containing Glutamine, Arginine & Omega 3 fatty acid) dissolved in water twice-a-day started within 48 hours of surgery]

A number of facts have been enumerated some of which are in accordance with literature while others differ.Conventional approach have been the routine practice of surgeons in R G Kar Medical College & Hospital.

In our hospital early oral diet along with immunonutrient supplementation is rarely performed. I took the opportunity to take up the prospective comparative study of effect of "early immunonutrients supplementation after enteric anastomosis in the prevention of post operative complications as compared to conventional approach".

Anastomotic Leak

The first criteria of comparison between these two groups were about the rate of anastomotic leaks detected radio-logically. This study shows an anastomotic leak in 8 patients of Conventional group as compared to 1 patient of immunonutrients group. P value was 0.0113 which is statistically significant. This signifies that feeding patients with immunonutrients early in postoperative is beneficial. This has been confirmed by studies done earlier.

Luigi Marano et al ²⁴et al showed that a beneficial effect of immunonutrients supplementation. Anastomotic leakage 2 (3.7 %) inimmunonutrition supplemented group as compared to 4 (7.3 %) in standard enteral nutrition group. P Value of 0.045 is statistically significant in this study.

A study done by SelimYigitYildiz²⁵ shows that administration of immunonutrition post operatively decreases the chances of anastomotic leak .P =0.018 in this study which is statistically significant.

Wound Infections

The second criteria of comparison between these two groups were rates of surgical wound infections.In this study it was found that patients on immunonutrients in early post operative period had less of wound infections (3 patients) as compared to those treated conventionally (9 patients).

Similar study done by Oliver Chow and Adrian Barbul ²⁶ in the year 2013 at , New Jersey concluded that immunonutrition have shown promising results in decreasing infectious complications but wound healing needs specific evaluation.

Similar study was done by Luigi Marano et al²⁷which showed 1.8% patients developed wound infections in immunonutrient group compared to 5.4% in the conventional group.

Abdominal Abscess

Another important criteria discussed in the study is the comparison between the two groups regarding the formation of abdominal abscess in the post-operative period.

In this study 7 patients in the conventional developed abdominal abscess as a postoperative complication compared to 1 patient on immunonutrient diet.P value for this data was 0.0226 which is

statistically significant. Similar study was done by SelimYigitYildiz²⁸ but it concluded into a statistically insignificant data (P=0.315).

Respiratory Tract infections

This study did not show any significant advantage of immunonutrient supplementation on the prevention of respiratory tract infections. It was found that 4 patients in conventional group developed respiratory tract infections as compared to 2 patients in immunonutrition group. The P value was 0.3894.

A study done by Pedro Moya²⁹ showed no significant advantage of immunonutrition enriched diet in preventing respiratory tract infections. Pneumonia occurred in 3.3% of patients without perioperative immunonutrition as compared to 1.6% in patients receiving immunonutrition diet. P value in this study was 0.408.

Study done by Stanislaw Klek³⁰showed similar results .29.41% of patients developed pneumonia in the standard enteral nutrition group as compared to 21.71% of patients of immunonutritiongroup.P value was 0.12322 which is insignificant.

Non Infectious Complications

Non-infectious complications in the post-operative period include a variety of conditions like Haemorrhage, Deep Vein Thrombosis, Pulmonary Embolism, Heart failure, Atelectasis, Paralytic illus& Wound Dehiscence etc.

Non-infectious complications in conventional group occurred in 5 patients as compared to 2 patients of immunonutrient group. P value is 0.2276.

This study concludes that not much significant improvement is noticed in the prevention of noninfectious complications after administration of immunonutrients.

Similar studies done outside are in concordance with this present study.

Study done by Marco Braga MD & Luca Gionatti MD³¹ named"Peri operative immunonutrition in patients undergoing cancer surgery" shows a similar result .Supplemented group had 8% patients with non-infectious complications as compared to 9% patients in control group. The P value of this study was 0.98 which is statistically insignificant.

Death

Comparison of mortality rates between both these groups did not yield any significant result. 2 patients of Conventional group lost their life during the course of treatment in the post operative period as compared to 1 patient of immunonutrient group. The P value is 0.5536 which is statistically insignificant.

A study comprising a larger sample size may give a better picture about mortality rates.

Studies none previously have shown a similar result as this study . Luigi Marano, MD, RaffaelePorfidia, MD³² had showed 1.8% mortality in both Standard enteral and immunonutrient supplemented group respectively. The P value was 0.325 which is statistically insignificant. Length of stay in Hospital

The mean length of stay in conventional group was 9.2 days as compared to 7.4 days of immunonutrient group. A decrease in mean length of stay in hospital by 1.8 days if immunonutrients are given in early postoperative period. The P value is 0.0043. Thus early feeding with immunonutrient decreases length of stay in hospital and thus decreases cost of treatment.

Studies done outside are also of similar view. A study done by Yan Zhang, YuanhuiGu, TiankangGuo et al 33 named "Perioperative immunonutrition for gastrointestinal cancer" shows perioperative Immunonutrition significantly reduced length of hospital stay (WMD, -2.62; 95% CI, -3.26 to -1.97; P < 0.01).

V. Conclusion

After comparing categorical and ordinal data of this study, some important facts have been noted regarding the early supplementation of patients with immunonutrients .There is an obvious benefit of giving diet enriched with Glutamine , L Arginine and Omega 3 fatty acids to post operated patients who have undergone gastrointestinal anastomosis. The rates of infectious complications have decreased especially wound infections, anastomotic leaks decreased,rates of abdominal abscess decreased & the mean length of stay in hospital decreased by 2 days approximately. Though this study does not show any significant difference in the mortality between these two groups still it have proved that supplementing early diet in post operated gastrointestinal surgery patients with immunonutrients do have a beneficial effect when compared to conventional Nil per Oral approach .The results of this study on the above parameters matches and is comparable with previous various studied performed worldwide.

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Table: Distribution of mean age, weight, pre-op albumin, POD 2 albumin, POD 8 albumin and Length of stay

	Group	Number	Mean	StdDev	Minimum	Maximum	Median	p-value
Age	Conventional	30	44.5000	14.7689	21.0000	71.0000	44.5000	0.1875
	Immunonutrient	30	49.8667	16.3596	25.0000	76.0000	47.5000	
Weight	Conventional	30	64.3000	9.8861	51.0000	88.0000	62.5000	0.8363
	Immunonutrient	30	63.7667	10.0230	49.0000	81.0000	62.0000	
PRE OP albumin	Conventional	30	3.6733	.6119	2.9000	5.1000	3.7000	0.8444
	Immunonutrient	30	3.8000	.5484	3.0000	5.0000	3.8000	
POD 2 albumin	Conventional	30	3.3300	.5466	2.6000	4.9000	3.3000	0.0111
	Immunonutrient	30	3.6967	.5366	2.8000	4.8000	3.6000	
POD 8 albumin	Conventional	30	3.3833	.4969	2.5000	4.6000	3.2500	0.0059
	Immunonutrient	30	3.7600	.5236	2.8000	4.8000	3.7000	
Length of stay	Conventional	30	9.2667	2.9587	6.0000	16.0000	8.0000	0.0043
,	Immunonutrient	30	7.4667	1.5025	6.0000	11.0000	7.0000	

Table: Distribution of parameters in two groups

	Table: Distribution of parameters in two groups					P value
		Conventional	Immunonutrient	TOTAL	Chi- square	1 value
Gender	Female	18	14	32	1.0714	0.3006
	Row %	56.3	43.8	100.0		
	Col %	60.0	46.7	53.3		
	Male	12	16	28		
	Row %	42.9	57.1	100.0		
	Col %	40.0	53.3	46.7		
Comorbidity	No	22	24		0.3727	0.5415
·	Row %	47.8	52.2			
	Col %	73.3	80.0			
	Yes	8	6			
	Row %	57.1	42.9			
	Col %	26.7	20.0			
Gastric CA	No	25	24	49	0.1113	0.7386
	Row %	51.0	49.0	100.0		
	Col %	83.3	80.0	81.7		
	Yes	5	6	11		
	Row %	45.5	54.5	100.0		
	Col %	16.7	20.0	18.3		
Colorectal CA	No	23	26	49	1.0019	0.3168
	Row %	46.9	53.1	100.0		
	Col %	76.7	86.7	81.7		
	Yes	7	4	11		
	Row %	63.6	36.4	100.0		
	Col %	23.3	13.3	18.3		
CROHN	No	30	30	60		
	Row %	50.0	50.0	100.0		
3.61 11	Col %	100.0	100.0	100.0	0.0500	0.5055
Miscellaneous	No Row %	11 52.4	10	21 100.0	0.0733	0.7866
benign	Col %	36.7	47.6 33.3	35.0		
		19	20	33.0		
	Yes Row %	48.7	51.3	100.0		
	Col %	63.3	66.7	65.0		
Anastomotic leak	Absent	22	29	51	6.4052	0.0113
Anastomotic leak	Row %	43.1	56.9	100.0	0.4032	0.0113
	Col %	73.3	96.7	85.0		
	Present	8	1	9		
	Row %	88.9	11.1	100.0		
	Col %	26.7	3.3	15.0		

Table: Distribution of parameters in two groups

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		Conventional	Immunonutrient	TOTAL	Chi-	P value
		Conventional	immunonati ient		square	
WOUND INF	Absent	21	27	48	3.7500	0.0528
	Row %	43.8	56.3	100.0		
	Col %	70.0	90.0	80.0		
	Present	9	3	12		
	Row %	75.0	25.0	100.0		
	Col %	30.0	10.0	20.0		
ABD ABCESS	Absent	23	29	52	5.1923	0.0226

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	Row %	44.2	55.8	100.0		
	Col %	76.7	96.7	86.7		
	Present	7	1	8		
	Row %	87.5	12.5	100.0		
	Col %	23.3	3.3	13.3		
RESP INF	Absent	26	28	54	0.7407	0.3894
	Row %	48.1	51.9	100.0		
	Col %	86.7	93.3	90.0		
	Present	4	2	6		
	Row %	66.7	33.3	100.0		
	Col %	13.3	6.7	10.0		
NON-	Absent	25	28	53	1.4555	0.2276
INFECTIOUS	Row %	47.2	52.8	100.0		
COMPLICATI	Col %	83.3	93.3	88.3		
ONS	Present	5	2	7		
	Row %	71.4	28.6	100.0		
	Col %	16.7	6.7	11.7		
DEATH	No	28	29	57	0.3509	0.5536
	Row %	49.1	50.9	100.0		
	Col %	93.3	96.7	95.0		
	Yes	2	1	3		
	Row %	66.7	33.3	100.0		
	Col %	6.7	3.3	5.0		

Dr.Debarshi Jana. "Effect of Early Immunonutrient Supplementation after Enteric Anastomosis in the Prevention of Post Operative Complications As Compared To Conventional Approach." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 18, no. 3, 2019, pp 50-56.