### **Original Research Article**

DOI: http://dx.doi.org/10.18203/2349-2902.isj20174107

# A prospective randomized controlled study: early enteral nutrition following gastrointestinal surgery

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Received: 14 August 2017 Accepted: 22 August 2017

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#### **ABSTRACT**

**Background:** The word anastomosis originates from the Greek word (ἀναστόμωσις) meaning communicating opening. Gut anastomosis is one of the frequently performed surgeries in both emergency and elective setup. Anastomosis following gut resections in emergency set up is mostly done due to traumatic rupture, benign or malignant perforation or obstruction and in certain other inflammatory conditions. Anastomosis is also done in some elective conditions like mostly due to malignancy of GI system. As conventional practice following gut anastomosis, patients are kept "NIL BY MOUTH" till bowel sounds return.

**Methods:** It's a prospective study, carried out over period of 18 months in Department of General Surgery, Sri Guru Ramdas Institute of Medical Sciences and Research, Vallah, Amritar. The objective of this study was to whether early enteral feeding within 48 hours of small gut anastomosis is tolerable to the patient. Whether early enteral feeding within 48 hours of small gut anastomosis is beneficial to the patient.

**Results:** This prospectively conducted comparative study was carried out on 60 patients, meeting inclusion criteria, undergoing gastrointestinal anastomosis either elective or emergency, in the Department of General Surgery, SGRD Medical College, between Jan 2012 to June 2013. Random selection of patients into group A (30) and group B (30) was done after having fulfilled inclusion and exclusion criteria. The group A was fed via enteral route within 48 hrs of enteric anastomosis. The group B was fed via enteral route after 48-72 hours or appearance of full peristaltic sounds following enteric anastomosis. These patients were followed in post-operative period for their drain output, any nausea, vomiting, or significant abdominal distension, prolonged ileus, clinical leakage, infective complications, hospital stay.

Conclusions: The following inferences can therefore be drawn from this study: Appearance of intestinal peristaltic sounds is earlier in early enterally fed group, Mean duration of post-operative hospital stay is lower in early enterally fed group, mean post-operative day 4 albumin level is higher in early enterally fed group. The rate of infective complications (UTI, RTI, wound complications) is equal in both the groups. The rate of clinical leakage, nausea/vomiting are equal in both the groups. The rate of re-exploration for anastomotic leakage is equal in both the groups.

**Keywords:** Anastomosis, Enteral, Groups

#### INTRODUCTION

The word anastomosis originates from the Greek word (ἀναστόμωσις) meaning communicating opening. Gut

anastomosis is one of the frequently performed surgeries in both emergency and elective setup. Anastomosis following gut resections in emergency set up is mostly done due to traumatic rupture, benign or malignant perforation or obstruction and in certain other inflammatory conditions. Anastomosis is also done in some elective conditions like mostly due to malignancy of GI system. As conventional practice following gut anastomosis, patients are kept "NIL BY MOUTH" till bowel sounds return. During this time period, patient remains with nasogastric tube for decompression of stomach and providing rest to the gut.

#### Rationality behind this practice is

- Postoperative gut dysmotility mainly affects stomach and colon along with small gut in a lesser magnitude
- To protect the anastomotic site by providing rest to the gut and avoiding passage of food through it.

Recently great emphasis has been paid on early enteral feeding within 6 to 24 hours after operation. However, in post-operative period, sometimes nutrition of the patient is maintained by TPN. Except being of high cost, TPN has its own complications like infection, metabolic disturbances and immunological disturbances. So, studies are now being conducted regarding feasibility of early enteral feeding.

#### Ideas behind early enteral feeding are as follows

- Gut secretes and reabsorbs about 7 liters of fluid per day irrespective of oral intake, so giving 'rest to gut and protecting anastomotic site' is based on a false notion
- Gut recovers from dysmotility within 24 to 48 hours in case of stomach and colon while 4 to 6 hours in case of small bowel<sup>1,2</sup>
- It prevents translocation of bacteria or virus by maintaining integrity of gut mucosa which may become atrophied if gut remains in rest<sup>3-5</sup>
- Many patients remain malnourished before operation; they are predisposed to more postoperative complications<sup>6,7</sup>
- Starvation reduces the collagen content in the scar tissue and diminishes the quality of healing, 8 whereas feeding reverses mucosal atrophy induced by starvation and increases anastomotic collagen deposition and strength.

So, on the basis of above ideas, now-a-days early enteral feeding in small gut anastomosis is undertaken.

#### **METHODS**

It's a prospective study, carried out over period of 18 months in Department of General Surgery, Sri Guru Ramdas Institute of Medical Sciences and Research, vallah, Amritar, Punjab, India.

The objective of this study was to whether early enteral feeding within 48 hours of small gut anastomosis is tolerable to the patient. Whether early enteral feeding

within 48 hours of small gut anastomosis is beneficial to the patient.

#### Specific objectives

Feasibility, safety and efficacy of early enteral feeding after small gut anastomosis in terms of morbidities like-Incidence of vomiting, Rate of anastomotic leak, Rate of infective complications and Length of post-operative hospital stays in days. Also, this study will focus on any difference in mortality and cost-effectiveness.

Patients admitted in emergency and elective surgical wards of SGRD Medical College. Informed consent was taken from patients participating in the study. From January 2012 to June 2013. With 60 patients and design of this study was randomized selected patients.

#### Inclusion criteria

- Patients undergoing gastric, small bowel, large bowel and uncomplicated simple biliary-enteric anastomosis on an emergency or elective basis
- Feeding proximal to anastomotic site within 24 hours following operation either per orally or through nasogastric tube.

#### Exclusion criteria

- The patient with ASA grade IV to VI
- Re-laparotomies following anastomosis
- Operation requiring operative time > 4 hours
- Post-operative patients requiring ventilator support
- Gross contamination of peritoneal cavity prior to surgery
- Immunocompromised patients
- Paediatric patients (<12 years)
- Pregnant patients
- Patients having stomas

A randomized prospective study between two groups

Group A - was fed within 48 hours after enteric anastomosis

Group B - was fed 48-72 hours after or sometimes even more following enteric anastomosis depending upon return of full peristaltic sounds.

#### Parameters to be studied

History of the patient, operative finding, site of surgery, whether any anastomosis was performed, whether pathology was benign or malignant, type of feed used, method of administration of feed, nitrogen balance and nutritional parameters like body weight, serum albumin, serum transferrin pre and post operatively. Observation of adverse clinical outcomes like anastomotic leakage, postoperative fever, wound infection, septicaemia,

pneumonia, vomiting, intra-abdominal collection, mortality. Routine haematological and biochemical investigations. Time of return of bowel sounds and passage of flatus and passage of stool, length of hospital stay, mortality and expense of treatment.

#### Study tools

Patient's informed consent form, B.H.T, O.P.D tickets, Discharge certificates, Bed side equipment like measuring tape, stethoscope, sphygmomanometer, Haematological and biochemical examination reports like complete haemogram, sugar, urea, creatinine, LFT, electrolytes. Proforma for tabulation of data.

#### Radiological

Straight x-ray chest, Straight x-ray abdomen, USG and CECT of abdomen as and when required.

#### Study techniques

Random selection of patients into group A (30) and group B (30) were done after having fulfilled inclusion and exclusion criteria. The group A was fed via enteral route within 48 hours of enteric anastomosis. The group B was fed via enteral route after 48-72 hours or appearance of full peristaltic sounds following enteric anastomosis. The dietary composition was of polymeric in nature as guided by hospital nutrient. Oral feed was started from 100ml/hr on day 1to 200 ml/hr on day 2. Subsequent feeding rate was dependent on patient's acceptance and status These patients were followed in post-operative period for their drain output, any nausea, vomiting, significant abdominal distension, prolonged ileus, anastomotic leakage ,any infective complications, duration of post-operative hospital stay.

#### Plan for analysis of data

The information obtained from this study was tabulated in a master chart and then statistically analysed, using standard methods like mean, standard deviation and frequency, coefficients of correlation and dispersion. Comparative analysis of benefits of early enteral feeding (<48 hours) on enteric anastomosis over that of the conventional delayed enteral feeding was done by using chi-square test and unpaired t-test.

#### Statistical methods

Data are expressed as mean±SD for continuously distributed variables and in absolute numbers and percentages for the discrete variables.

#### **RESULTS**

This prospectively conducted comparative study was carried out on 60 patients, meeting inclusion criteria, undergoing gastrointestinal anastomosis either elective or

emergency, in the Department of General Surgery, SGRD Medical College, between Jan 2012 to June 2013. Random selection of patients into group A (30) and group B (30) was done after having fulfilled inclusion and exclusion criteria. The group A was fed via enteral route within 48 hours of enteric anastomosis. The group B was fed via enteral route after 48-72 hours or appearance of full peristaltic sounds following enteric anastomosis. These patients were followed in post-operative period for their drain output, any nausea, vomiting, or significant abdominal distension, prolonged ileus, clinical leakage, infective complications, hospital stay.

#### Demographic profile

Age

To begin with the, distribution of patients according to their ages in our study was observed that in both the groups, most of the patients are in the age group of 21 years to 40 years. Mean age for group A is 38.1 years (SD-12.104) and for group B is 36.133 years (SD-13.151). Applying unpaired t-test, p value is found not to be significant (p=0.5491). So, both the groups are comparable in respect to their age distribution.

#### Sex distribution

In group A, out of 30 patients, 9 are females and 21 are males. In group B, out of 30 patients, 7 are females and 23 are males. In group A 30% of patients are female, in group B only 23.33% patients are female. Applying the chi-square test, p (Yate's correction) value is found not to be significant (p=0.559).

Distribution of cases according to emergency and elective

In group A, 12 cases were done in emergency (40%) and in group B, 10 cases were done in emergency (33.33%). Applying the chi-square test (Yate's correction) value is not seen to be significant (P=0.7888). So, both the groups are comparable in respect to their distribution as emergency and elective cases.

Distribution of cases according to benign and malignant

In group A, out of 30 cases only 12 cases were found to be malignant and in group B only 11 cases are found to be malignant. There are 40% cases malignant in group A and 36.67% cases are malignant in group B. Both the groups are comparable in respect to their distribution as malignant and non-malignant cases, as p value of the chisquare is 1 (Yate's correction).

Distribution of preoperative albumin in patients of both the groups

The pattern of distribution of preoperative albumin level in both the groups was done, the mean preoperative albumin levels in group A and group B are 3.513gm/dl (SD-0.456) and 3.463 gm/dl (SD-0.466) respectively. Applying unpaired t-test, p value is seen not to be significant (p=0.6760). So, both the groups are comparable for their preoperative albumin level distribution.

#### Presence of gangrenous gut

During operative procedure, out of 30 patients in group A, only 6 patients were found to have gangrenous gut as shown in Table 1. Only 4 patients were found to have gangrenous gut in group B. Both the groups are comparable in respect to distribution of gangrenous gut as p value of the chi-square test is 0.7290 (Yate's correction).

Table 1: Presence of gangrenous gut.

Group	Gangrenous gut	Healthy gut
A	6 (20%)	24 (80%)
В	4 (13.33%)	26 (86.67%)

#### Anastomosis Stapled versus Hand sewn

In group A, out of 30 anastomoses 4 anastomosis (13.33%) were done by using surgical staplers. In group B, out of 30 anastomoses 6 anastomosis (20%) were done by using surgical stapler. Applying the chi-square test, p (Yate's correction) value is found not significant (p=0.7290). So, both the groups are comparable.

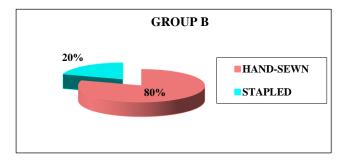


Figure 1: Distribution of anastomosis in percentage in group B.

Distribution of patients receiving steroid therapy

Only one patient in group B receiving inhalational steroid therapy for COPD. But no patient of Group A received any form of steroid therapy. Applying the chi-square test, p (Yate's correction) value is found not to be significant (p=1). So, both the groups are comparable for distribution of patients receiving steroid therapy.

Prevalence of co-morbidities in both groups

In group A, there are 5 patients who were suffering from different comorbid conditions (Figure 3). Among them, 3 patients were suffering from hypertension and other 2

patients are suffering from type 2 diabetes mellitus. Both the comorbid conditions were under controlled in every patient by oral medications.

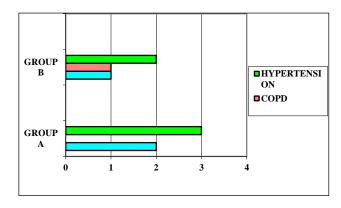


Figure 2: Prevalence of comorbidities.

In group B, there are 4 patients who are suffering from different comorbid conditions (Figure 2). Among them, 2 patients were suffering from hypertension and other 2 patients were suffering from type 2 DM and COPD. All the comorbid conditions were controlled in every patient by oral medications and inhalational therapy.

Applying the chi-square test, p (Yate's correction) value is not found to be significant (p=1). So, both the groups are comparable in terms of distribution of comorbidities. So, both the groups (A and B) are comparable for their distribution of age, sex, emergency-elective cases, malignant- non-malignant, presence of gangrenous gut, preoperative haemoglobin level, preoperative albumin level, stapled hand sewn anastomosis, receiving of steroid therapy, receiving of chemotherapy and co-morbidities.

Appearance of intestinal peristaltic sounds (IPS)

Figure 3 (line diagram) shows the distribution of time of appearance of IPS in both the groups. The mean time of appearance of IPS in group A and group B were 42.8 hours (SD=10.772) and 53.6 hours (SD=13.64) respectively.

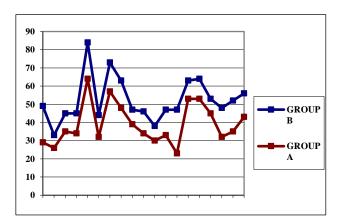


Figure 3: Distribution of time of appearance of IPS.

The time of appearance of IPS in group A is earlier than that of group B. Applying the unpaired t-test, p value is found to be significant (p=0.0012). So, the time difference of appearance of IPS in both the group is statistically significant.

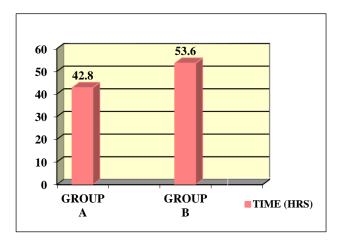


Figure 4: Mean time of appearance of IPS.

Incidence of clinical leakage

The table (Table 2) shows out of 30 patients in group A, 4 patients developed clinical evidence of leakage of gastrointestinal anastomosis. In group B, out of 30 anastomosis, 2 patients developed clinical leakage. The leakage rates of gastrointestinal anastomosis in group A and group B were 13.33% and 6.67% respectively.

Table 2: Incidence of clinical leakage.

Group	Clinical leakage (yes)	Clinical leakage (no)
A	4(13.33%)	26(86.67%)
В	2(6.67%)	28(93.33%)

The clinical leakage rate in group A is higher than that of group B. Applying the chi-square test, p value (Yate's correction) is found not to be significant (p=0.6670). So, the difference in clinical leakage rate in both the groups is not statistically significant.

Rate of wound infection

Table of Table 3 shows that out of 30 patients of group A, 8 patients developed wound infection and out of 30 patients of group B, 6 patients developed wound infection.

The rates of wound infection in group A and group B are 26.67% and 20%. The rate of wound infection is higher in group A than that of group B. Applying the chi-square test, p value (Yate's correction) is found not to be significant (p=0.7602). So, the difference in rate of wound infection in both the groups is not statistically significant.

Bar diagram of Table 3 shows that out of 8 wound infection of group A, 5 patients suffered from major wound infection and other 3 suffered from minor wound infection. In group B, 4 patients suffered from major wound infection and other 2 suffered from minor wound infection.

**Table 3: Distribution of wound infection.** 

Group	Wound infection present	Wound infection absent
A	8 (26.67%)	22 (84.31%)
В	6 (20%)	24 (80%)

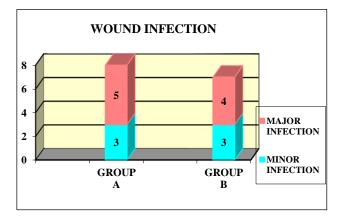


Figure 5: Number of major and minor wound infection.

Major wound infection requires repeated wound debridement at operating room with proper antibiotic therapy and regular dressing at wards with proper antibiotic therapy.

Distribution of post-operative day 4 albumin level

Our study shows the distribution of post-operative day 4 albumin level in both the groups. The mean of post-operative day 4 albumin level in group A and group B were 3.147 gm/dl (SD=0.445) and 2.747 gm/dl (SD=0.475) respectively.

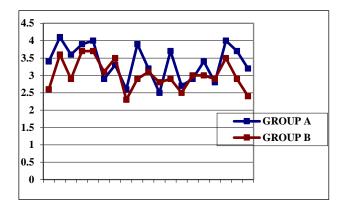


Figure 6: Distribution of post-operative day 4 albumin level.

The mean of post-operative day 4 albumin level in group A is higher than that of group B. Applying the chi-square test, p value is found to be significant (p=0.0014). So, the difference of mean of post-operative day 4 albumin level in both the groups is statistically significant.

#### Post-operative hospital stays

Our study shows the distribution of duration of post-operative hospital stay (days) in both the groups. The mean duration of post-operative hospital stay in group A and group B were 7.4 days (SD=4.966) and 10.133 days (SD=5.09) respectively. The mean duration of post-operative hospital stay in group B is higher than that of group A. Applying the unpaired t -test, p value is found to be significant (p=0.0396). So, the difference of mean duration of post-operative hospital stay in both the groups is significant

#### **Mortality**

It has been observed in our study that two mortalities in group A, but no mortality in group B. The difference of mortality in these two groups is not statistically significant (p=0.472).

In group A, one patient died due to severe sepsis following clinical leakage of gastrointestinal anastomosis. The other patient died due to acute myocardial infarction with uncontrolled blood pressure in post-operative period in the presence of evidence of clinical anastomotic leakage.

#### **DISCUSSION**

Traditionally after abdominal surgery, the passage of flatus or bowel movement has been the clinical evidence for starting an oral diet. It is customary to keep the patients "nil by mouth" after gastrointestinal anastomosis till patient passes flatus. Adequate nutrition has always been a major goal in postoperative care. It is also being increasingly recognized now that withholding oral feeds for few days after surgery in such cases leads to nutritional depletion and its consequences. Lewis et al in his meta-analysis of 11 studies along with some other studies have examined the role of early feeding after gastrointestinal anastomosis and found that it improved immunocompetence, decreased septic complications, improved wound healing and possibly improved anastomotic strength. 9-13

The mean age of the patients in group A was 38.1 (SD=12.104) and 36.133 (SD=13.151) years in group B and was comparable. In group A 30% and 23.33% in group B were females. These groups were comparable for the for the distribution of emergency-elective cases, malignant - nonmalignant cases, presence of gangrenous gut, preoperative hemoglobin level, preoperative albumin level, stapled-hand sewn anastomosis, receiving of

steroid therapy, receiving of chemotherapy and comorbidities.

In our study majority of the cases of both the groups underwent enteric anastomosis for closure of stoma(ileostomy/colostomy), malignancy of gut requiring resection and anastomosis of stomach, small gut, large gut. All the operations in both the groups are done under general anaesthesia.

In the present study, abdominal drain was put in all cases in group A and group B which was comparable. In a similar study by Stewart et al on early feeding after elective open resections, intraabdominal drainage was done in 37% cases of study group and 40% in control group.14 The present study out of 4 cases (13.33%) in group A and 2 cases (6.67%) in group B who had post-operative leak, re-exploration was done in 2 patients in group A and 1 patient in group B. The drain was able to pick up all anastomotic leakage in both the groups and some cases of anastomotic leakage manifested as fecal/bilious discharge from main abdominal wound.

Enteral feed was started within 48 hours of surgery and it was well tolerated in 22 (73.33%) cases of group A and 25 (16.67%) cases of group B. Remaining 8 cases (26.67%) of group A and 5 cases (16.67%) of group B could not tolerate early enteral feeds. Oral feeding had to be withheld for next 6-12 hours, then all the patients could tolerate feed in small quantities. In other similar studies in the past, feeding was started 48-72 hours following operation and patients tolerated feed.<sup>5-8</sup> The tolerance to early oral feed in the present study is comparable to the results of the previous studies. In study conducted by Stewart et al, tolerance to early oral feed is much less (65%) in comparison to other studies, possibly due to the fact that feed was started within 4 hours of surgery when residual effect of anaesthetic drugs is still present. However, another important observation is that tolerance to oral feeds is same in present as well as most of the previous studies despite the fact that early oral feed was started within 48 hours in the present study as in all other studies, oral feed was started within 24-72 hours of surgery. this indicates that oral feed can safely be started after 48 hours of surgery with good tolerance because effect of anaesthetic drugs is over by that time.

In the present study, 26.67% of patients in group A and 16.67% patients in group B complained of nausea and vomiting after the start of oral feeds which was comparable between the two groups. The incidence of nausea and vomiting, although not statistically significant, was more in group A as compared to group B. Intestinal peristaltic sounds appeared in a significantly shorter period of time in group A (mean 42.8 hours; SD=10.772) as compared to group B(mean 53.6 hours; SD=13.64) (p<0.05). In a similar study by Fanaie et al there was no statistically significant difference in the appearance of bowel sounds among cases of two groups (0.5,0.6 versus 0.5,0.5 days) (p=0.65).

Serum albumin level estimation was done in preoperative period and on day 4 in post-operative period in all the cases of both the groups. Values of the preoperative serum albumin were comparable among cases of two groups(p>0.05). However, in post-operative day 4 serum albumin values were significantly more in group A compared to group B (p<0.05). This occurred possibly due to early oral feeding which helped in improvement in nutritional status of patients of group A.

In the present study 8 cases (26.67%) in group A and 6 cases (20%) in group B had wound infection which was not statistically significant (p<0.05). The results of meta-analysis of 11 studies by Lewis et al have also shown that incidence of wound infection, although not statistically significant, is less in early fed group (p=0.074). The reverse findings have been observed in present study, although not statistically significant (p<0.05).

In the present study 6.67% cases in group B and 13.33% cases in group A had anastomotic leak which was comparable (p>0.05). In group A, out of 4 cases of intestinal leakage, first patient had undergone right hemicolectomy with ilio-colic anastomosis and the leakage was managed by forming an ileostomy. The second case in group A was found to have ileal perforation and undergone ileo-ileal anastomosis. This patient had undergone re-exploration and ileostomy. but the patient died due to severe sepsis. The third case had undergone left hemicolectomy and anastomosis. The leakage was managed conservatively as it formed a controlled external fistula without any features of sepsis. The fourth case in group A had undergone left hemicolectomy and colorectal anastomosis. The patient died on 5th post-operative day due to acute myocardial infarction. In group B, out of two cases of intestinal leakage, first case had undergone ileoileal anastomosis for ileal perforation. This case was managed by performing proximal ileostomy. Second case of leakage occurred following colostomy closure. This case was managed conservatively as it formed controlled external fistula without any features of sepsis.

In the past, various workers have observed that wound healing as well as anastomotic strength improves in cases of early oral feeding.<sup>2,4</sup> In the previous studies although incidence of postoperative leak is mentioned, but there is no mention regarding fate and further management of these cases.

Few cases of post-operative respiratory tract infections, urinary tract infections were encountered in both the groups and on statistical analysis there was no significant difference. In the meta-analysis conducted by Lewis et al, the incidence of pneumonia and intra-abdominal abscess was less in study group patients but the results were not statistically significant (p=0.85 and 0.84 respectively). <sup>10</sup>

In the present study, the mean duration of postoperative hospital stay was 7.4 days (SD=4.966) in group A and

10.133 days (SD=5.09) in group B and the difference was statistically significant (p<0.05). Duration of hospital stay in present study is comparable with the previous studies except the study by Kamei et al where postoperative hospital stay is much longer. It is possibly due to the fact that Kamei et al conducted their study in patients undergoing radical gastrectomy for carcinoma stomach that required prolonged hospitalization. One significant observation made by all these workers including present study is that post-operative hospital stay is significantly shorter in group A cases as compared to group B cases. It is possibly due to the fact that early feeding helps in early bowel movements, faster recovery, less post-operative complications, leading to early discharge from hospital.

#### **CONCLUSION**

The following inferences can therefore be drawn from this study:

- Appearance of intestinal peristaltic sounds is earlier in early enterally fed group
- Mean duration of post-operative hospital stay is lower in early enterally fed group
- Mean post-operative day 4 albumin level is higher in early enterally fed group
- The rate of infective complications (UTI, RTI, wound complications) is equal in both the groups.
- The rate of clinical leakage, nausea/vomiting are equal in both the groups
- The rate of re-exploration for anastomotic leakage is equal in both the groups.

On the basis of the above findings, we can conclude that the conventional wisdom of withholding enteral feeds for prolonged periods to coincide with the appearance of peristaltic sounds might not stand the test of time. The practice of early enteral feeding doesn't have any impact on anastomotic outcome. However further large volume studies will be required to justify such an approach.

Funding: No funding sources Conflict of interest: None declared

Ethical approval: The study was approved by the

institutional ethics committee

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Cite this article as: Bajwa RS, Brar N.

A prospective randomized controlled study: early enteral nutrition following gastrointestinal surgery. Int Surg J 2017;4:3249-56.