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EARLY ENTERAL FEEDING WITHIN 24 HOURS OF ELECTIVE GASTROINTESTINAL SURGERY VERSUS CONVENTIONAL NOTHING PER ORAL-A PROSPECTIVE CONTROLLED INTERVENTIONAL STUDY CONDUCTED AMONG ADULT POPULATION IN A TERTIARY CARE HOSPITAL IN EASTERN INDIA.

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Abstract

Background and objective: Traditionally the patients are kept on fasting till recovery of gut motility following gastrointestinal surgery to prevent postoperative vomiting, rupture of anastomosis and other known complications. The study was carried out to assess whether a period of postoperative fasting has a clear advantage over early enteral feeding following gastrointestinal surgery, particularly intestinal resection and anastomosis, in terms of outcomes mentioned above alongside pneumonia, sepsis, intraabdominal abscess, length of hospital stay and mortality.

Materials and method: Following approval of institutional ethics committee and written informed consent from the patients posted for elective gastrointestinal surgery, this prospective controlled interventional study was conducted by randomly allocating participants as per defined inclusion and exclusion criteria to one of the two groups: Early enteral feeding (EEF) and Nothing per oral (NPO), with thirty-three in each arm. Following surgery, each participant was managed prospectively and evaluated against predetermined outcomes. Appropriate statistical principles were applied for calculation of significance level (P= 0.05 and below).

Result: Early feeding significantly reduced the risks of postoperative wound infection, pneumonia, fever and hospital stay, while no clear advantage was observed in terms of postoperative nausea and vomiting, abdominal distension, anastomotic leakage and mortality in the conventional delayed feeding patients.

Conclusion: It does not seem rational to keep patients in fasting after elective gastrointestinal resection-anastomosis as early feeding clearly has an edge in postoperative recovery and reduced

hospital stay. However, multicentric trials are recommended to confirm or refute the observations of the current study.

Keywords: Delayed enteral feeding, early enteral feeding, gastrointestinal resection and anastomosis, nil by mouth, nothing per oral.

Introduction

Background and rationale: Traditional practice following gastrointestinal (GI) surgery is to keep the patient on no feed until the signs of return of bowel motility appears to prevent postoperative nausea and vomiting (PONV) and allow the anastomotic site to heal without the stress of passage of food. However, it is unclear whether deferral of enteral feeding is actually beneficial. [1,2] On the other hand, evidence of clinical studies and animal experiments suggest initiation of enteral feeding is advantageous with respect to reduction in morbidity and improved wound healing. Earlier studies were conducted in both elective and emergency setting, thereby actually obscuring the beneficial effects, if any, in the early feeding group due to simultaneous presence of multiple comorbidities associated with emergency GI anastomosis. Hence, the rationale of the study is to search for an effective economic postoperative management in elective GI surgeries, thereby reducing hospital stay and incidence of postoperative complications in a part of the world where delayed postoperative feeding is still preferred.

Specific objective of research is to compare the feasibility, safety and efficacy of early enteral feeding within 24 hours with conventional delayed mouth feeding after elective GI surgeries, especially resection and anastomosis.

Materials and Methods

Following approval of the Institutional Ethics Committee (IEC) and obtaining separate written informed consents for elective surgery and voluntary participation in the study from the adult patients, this prospective controlled interventional study was conducted in a span of eighteen months in a tertiary care hospital in the eastern zone of India as per following inclusion and exclusion criteria:

Inclusion criteria: (1) Adult persons, (2) Both sexes, (3) Patients undergoing elective GI surgeries, especially resection and anastomosis.

Exclusion criteria: (1) Patients needing emergency procedures, (2) Postoperative medical and surgical complications except the expected outcomes like PONV, wound infection, anastomotic leakage, pneumonia, abdominal distension, prolonged hospital stay due to any such causes and death, (3) Uncontrolled diabetes mellitus and (4) Spinal injury.

Study variables: (1) Independent variables like age and sex, (2) Dependent variables like anastomosis leakage, infection, length of hospital stays etc.

Study population: The participants visiting the outpatient department of the hospital and needing planned surgical intervention were randomly allocated in one of the two groups: (1) early enteral feeding (EEF) group and (2) conventional nothing per oral (NPO) group following necessary GI surgery as per the patient's condition and the operating surgeon's decision and approach. Patients not in need of resection-anastomosis following exploratory laparotomy were disqualified from the study and the deficit was made up from additional allowances as per sample size calculation (vide infra). Routine preoperative investigations done and anesthetic fitness was obtained prior to elective surgery.

Sample size calculation: The sample size per group with a significance level of 0.05 (two-sided), 90% power, mean hospital stay of four days or more, group standard deviation (SD) of five days estimated from available resource came out to be thirty. [3] An additional six were included to cater the dropouts. Hence, a total of sixty-six (N=66) participants were included.

Study procedure: In the group EEF, patients were commenced on oral sips of 5% dextrose for an hour after removal of nasogastric tube following six hours of reversal from anaesthesia. If this was tolerated, they were graduated to 25 ml per hour of low glycemic index powder enriched with protein, prebiotics and monounsaturated fatty acids for the next six hours. Patients tolerating well were shifted

to liquid diet, followed by light diet. Episodes of abdominal distension and bilious vomiting were noted and those with two episodes of such vomiting along with distension were stopped oral feeding. In the conventional group NPO, initiation of oral feeding was commenced upon resumption of bowel sound, passage of flatus or stool. They were gradually shifted to oral sips, oral clear fluids, light diet, semisolid diet and normal diet.

Outcome assessment: The participants were noted for wound infection (assessed on CDC criteria for surgical site infection, SSI), anastomotic leak (based on discharge of intestinal contents from incision or drain, localized or generalized peritonitis, fever or intraabdominal abscess on ultrasound or computed tomography scans), infection (clinically, complete blood count, sepsis screen), length of hospital stays.[4]

Follow-up protocol: Initial postoperative follow-up after two weeks from discharge, repeated after two weeks. Patients needing relaparotomy for complications were managed accordingly.

Statistical analysis: Data were entered into a Microsoft excel spreadsheet and analyzed by SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp (2017); summarized as mean±SD for numerical variables, count and percentage for categorical variables. Chi-square test was applied wherever necessary. $P \leq 0.05$ was considered statistically significant at 95% confidence interval.

Results

Age of participants ranged between 24 and 50 years with the largest proportion between 31-40 years in both groups with male preponderance (22 against a female population of 19). Average duration of surgery in group EEF was 60 minutes against 45 minutes in NPO group. Postoperative abdominal distension occurred in five (15.2%) patients in EEF, compared to four (12.1%) in NPO (P=1) **[Table 1].** The study showed two (6.1%) patients having PONV in EEF in comparison to six (18.2%) in NPO, though statistically insignificant (P=0.26) **[Table 2].** Fever was significantly less in EEF with only two (6.1%) patients against ten (30.3%) in NPO (P=0.02) **[Table 3].** Wound infection was significantly less in EEF with three (9.1%) against thirteen (39.4%) in NPO (P=0.009) **[Table 4]** along with significantly less incidence of pneumonia of two (6.1%) in EEF, compared to thirteen (39.4%) in NPO (P=0.003) **[Table 5].** Mean length of hospital stay was shorter in EEF than NPO (P=0.001) **[Table 6].** No clear advantage was observed in NPO in terms of anastomosis leakage and postoperative mortality as evidenced by the P-values of 0.6 **[Table 7]** and 0.35 **[Table 8]** respectively. Total dropout of the study population finally came to be zero.

Discussion

Mean age (mean±SD) in EEF was 37.36±7.96 years and 38±7.33 years in NPO (P=0.54). EEF had a male preponderance of 22 (66.7%) over female of 11 (33.3%) almost similar to Kishore K et al.[5] Lewis SJ et al found that early feeding reduced the risk of infection (relative risk 0.72, 95% confidence interval 0.54 to 0.98, P=0.04) and mean length of hospital stay.[6] Similarly significant risk reduction was observed in EEF group in terms of postoperative wound infection and pneumonia as far as it goes with the present study. Similar observations were made in earlier studies by Vaishnani B et al, Andersen HK et al and Malhotra et al.[7,8,9] No clear advantage was observed in NPO with respect to PONV in elective GI resection. Again, no clear advantage was seen in complications like anastomotic leak (3% in EEF against 9.1% in NPO with p=0.6) and mortality (P=0.35). Similar findings were obtained by Sheth JY et al, Roy A et al and Bajwa RS et al.[3,10,11] Hence, based on the recorded data and statistics, the study conclusively showed that enteral feeding had a better outcome than conventional delayed feeding in terms of shorter hospital stay, improved wound healing and significantly less chances of infective complications. However, no significant difference was obtained between two groups in terms of abdominal distension, vomiting and anastomotic dehiscence. Therefore, it can be concluded that early enteral feeding is safe, effective and feasible in postoperative patients of elective gastrointestinal resection and anastomosis. Whereas utmost care was taken to

safeguard the internal validity of the study within the limitations of a single center based single blinded research protocol, chances of hospital bias and presence of confounding factors like associated comorbidities of the participants remains a possibility. Hence, larger multicentric double blinded trial involving a team of researchers is recommended to test the external validity of the findings of the current study.

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Tables

Table 1: Distribution of abdominal distension.

Abdominal distension	Group-EEF	Group-NPO	Marginal row total
No	28 (28.5)	29 (28.5)	57
Yes	5 (4.5)	4 (4.5)	9
Marginal column total	33	33	66 (Grand total)

Chi-square value with Yate's correction (1, N=66) = 0, *P*=1. Association of abdominal distension versus group was not significant at *P*<0.05. Numbers inside the parenthesis in each cell indicates expected cell total.

Table 2: Distribution of vomiting.

Vomiting	Group-EEF	Group-NPO	Marginal row total
No	31 (29.0)	27 (29.0)	58
Yes	2 (4.0)	6 (4.0)	8
Marginal column total	33	33	66 (Grand total)

Chi-square value with Yate's correction (1, N=66) = 1.2802, *P*=0.257867. Association of vomiting versus group was not significant at *P*<0.05. Numbers inside the parenthesis in each cell indicates expected cell total.

Table 3: Distribution of fever.

Fever	Group-EEF	Group-NPO	Marginal row total
No	31 (27.0)	23 (27.0)	54
Yes	2 (6.0)	10 (6.0)	12
Marginal column total	33	33	66 (Grand total)

Chi-square value with Yate's correction (1, N=66) = 4.9907, *P*=0.025483. Association of fever versus group was significant at *P*<0.05. Numbers inside the parenthesis in each cell indicates expected cell total.

Table 4: Distribution of wound infection.

Wound infection	Group-EEF	Group-NPO	Marginal row total
No	30 (25.0)	20 (25.0)	50
Yes	3 (8.0)	13 (8.0)	16
Marginal column total	33	33	66 (Grand total)

Chi-square value with Yate's correction (1, N=66) = 6.6825, *P*=0.009736. Association of wound infection versus group was significant at *P*<0.05. Numbers inside the parenthesis in each cell indicates expected cell total.

Table 5: Distribution of pneumonia.

Pneumonia	Group-EEF	Group-NPO	Marginal row total
No	31 (25.5)	20 (25.5)	51
Yes	2 (7.5)	13 (7.5)	15
Marginal column total	33	33	66 (Grand total)

Chi-square value with Yate's correction (1, N=66) = 8.6275, *P*=0.003311. Association of pneumonia versus group was significant at *P*<0.05. Numbers inside the parenthesis in each cell indicates expected cell total.

Table 6: Distribution of mean length of hospital stay.

	Group	Number	Mean	SD	Minimum	Maximum	Median	*P*-value
Length of hospital stay	**EEF**	33	8.0606	5.7388	5.0000	30.0000	6.0000	0.001
	NPO	33	13.2500	6.4758	7.0000	40.0000	11.0000	

In group EEF, mean length of hospital stay (mean±SD) of patients was 8.0606±5.7388. In group NPO, mean length of hospital stay (mean±SD) of patients was 13.2500±6.4758. Distribution of mean length of hospital stay was statistically significant (*P*=0.001).

Table 7: Distribution of anastomosis leakage.

Anastomosis leakage	Group-EEF	Group-NPO	Marginal row total
No	32 (31.0)	30 (31.0)	62
Yes	1 (2.0)	3 (2.0)	4
Marginal column total	33	33	66 (Grand total)

Chi-square value with Yate's correction (1, N=66) =0.2661, *P*=0.60594. Association of anastomosis leakage versus group was not significant at *P*<0.05. Numbers inside the parenthesis in each cell indicates expected cell total.

Table 8: Distribution of mortality.

Mortality	Group-EEF	Group-NPO	Marginal row total
ALIVE	32 (30.5)	29 (30.5)	61
DEATH	1 (2.5)	4 (2.5)	5
Marginal column total	33	33	66 (Grand total)

Chi-square value with Yate's correction (1, N=66) =0.8656, *P*=0.352184. Association of mortality versus group was not significant at *P*<0.05. Numbers inside the parenthesis in each cell indicates expected cell total.

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