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Original Research Article

A prospective study conducted in a tertiary care hospital in eastern Rajasthan on the function of a multimodal perioperative management protocol in colorectal cancer surgery

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ABSTRACT

Background: For colorectal surgery, the enhanced recovery after surgery (ERAS) group has conducted a thorough analysis of perioperative treatment. When combined, a series of operations known as colorectal resection result in a shorter duration of stay, fewer problems, and an early recovery of gut function. Until recently, it was considered typical to stay in the hospital for 10 to 14 days after a big bowel resection. This study aimed to study the effects of a multimodal perioperative care protocol in patients undergoing surgery for colorectal cancer in a tertiary care hospital in eastern Rajasthan, India.
Methods: This was prospective randomized-controlled trial. Patients who are undergoing elective colorectal cancer surgery in tertiary care hospital (Sawai Man Singh hospital, Jaipur, Rajasthan) in year 2016 -17.
Results: Hospital stays were 6.64±0.842 (median 6-9) and 8.25±1.52 (median 6-12) days (p=0.002) for 30 patients (n=14 in the multimodal group and 16 in the control group), respectively. Complication rates were 13.40% and 20.31% (p=0.019), 30-day readmission rates were 14.28% and 25% (p=0.029), and mortality rates were 7.14% and 12.5% in the multimodal and control groups.
Conclusions: Complications, readmission rates, and death were all considerably lower in the multimodal group compared to the control group following the implementation of the multimodal perioperative treatment protocol during the hospital stay for colorectal cancer.

Keywords: Colorectal, Control, ERAS, hospital stay, Multimodal, Perioperative

INTRODUCTION

Complication rates for patients undergoing colorectal surgery, which involves bowel resection, can range from 15% to 20%.[1-3] These issues may cause a six-to ten-day postoperative hospital stay.[4] Extended hospital stays following colorectal surgery can have a substantial financial impact on health care systems. Kehlet et al were the first to provide a detailed description of a specific procedure known as the "fast-track" or "enhanced recovery after surgery" protocol, which aimed to shorten the period of hospital stay following colorectal surgery and might potentially cut it down to a mean of 4 days.[5] Hospital groups have proposed a number of protocols that include different individual fast-track elements for preoperative, intraoperative, and postoperative care. These include counselling and feeding prior to surgery,

not preparing the patient's bowels, high oxygen concentrations during the procedure, actively preventing hypothermia, and not routinely using nasogastric tubes and drains.[6-14] A meta-analysis of six trials (three RCTs and three CCTs) including 512 patients was carried out by Wind et al and shown that patients in fast-track programs have lower morbidity and primary hospital stays following elective colorectal surgery.[15] But in 2000, a clinical approach to hasten recovery following colonic resection was outlined by Basse and Kehlet, significantly reducing length of stay. A median stay of two days and a 15% readmission rate were reported in their study.[16-19]

Our research aimed to reduce the operative stress response, hasten recovery, lessen complications, shorten hospital stays, lower the readmission rate, and lower mortality.

METHODS

Study design and setting

This was prospective randomized control study. Patients who are undergoing elective colorectal cancer surgery in tertiary care hospital (Sawai Man Singh hospital, Jaipur, Rajasthan) in year 2016 -17.

Inclusion criteria

Patients who are undergoing elective colorectal resection for cancer with informed consent were included.

Exclusion criteria

Patients with metastatic disease, clinical depression, combined procedures with other surgical specialty, patients who does not give consent and patients who underwent neoadjuvant chemoradiotherapy were excluded.

Sample size

Sample size was calculated to be 30 in both multimodal and control groups. The study was powered 80% (α=0.05, β=0.80) to assuming the difference in mean duration of nasogastric tube removal and early feeding to be 1.1 days and SD = 1 in multimodal and control group. Hence for study purpose 30 subjects will be required. Randomization of patients are done by Simple block randomization method (Figure 1).

Methodology

Multimodal patients receive intravenous fluid restriction, unrestricted oral intake with prokinetic medicines, early ambulation, early nasogastric tube removal, early enteral feeding, and preoperative antimicrobial prophylaxis. Under control patients who don't get multimodal care throughout the perioperative stage.

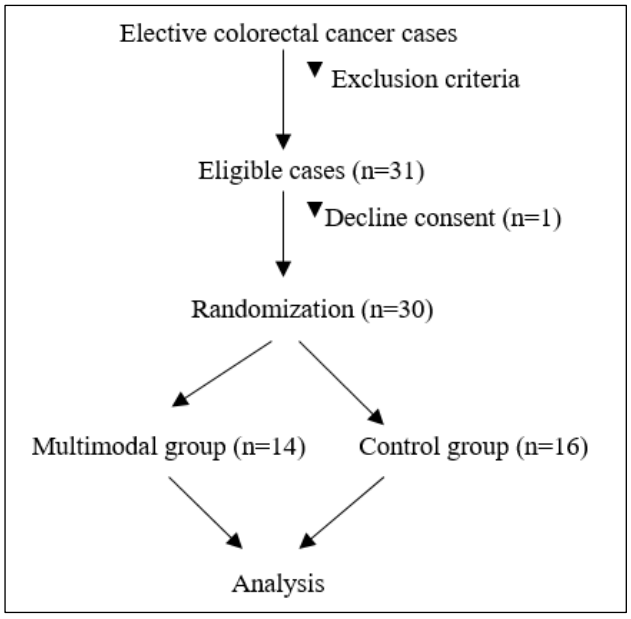

Figure 1: Flow chart of plan of action.

Statistical analysis

The unpaired t-test will be utilized to assess continuous data in both the multimodal and control groups. Proportions and percentages are used to express continuous data. The mean±SD is used to express continuous data. Continuous data trends would be maintained at a 95% confidence interval (p value<0.05).

RESULTS

In the multimodal group, the mean days (±2SD) for various recovery milestones were significantly shorter compared to the control group: NG tube removal (1.35±1.99 vs. 2.06±1.54 days, p = 0.038), postoperative mobilization (1.0±0.78 vs. 1.68±1.40 days, p=0.003), bowel sounds (1.92±0.95 vs. 2.64±1.20 days, p=0.001), flatus passage (2.42±1.02 vs. 3.31±1.40 days, p=0.001), ambulation (2.78±1.78 vs. 4.0±2.42 days, p=0.004), oral feeding (2.21±1.73 vs. 3.06±2.07 days, p=0.021), normal/solid diet tolerance (3.85±1.32 vs. 4.81±2.09 days, p=0.007), urine catheterization (2.71±1.22 vs. 3.37±2.05 days, p=0.044), fluid restriction (2.42±1.09 vs. 3.65±1.07 days, p=0.001), and hospital stays (6.64±1.68 vs. 8.25±3.04 days, p=0.002). Overall, the multimodal approach resulted in significantly faster recovery across all measured parameters compared to the control group (Table 1).

In the multimodal group, complications such as wound infection (25%), anastomotic leak (25%), urinary/sexual dysfunction (0%), stoma complications (0%), chest infection (25%), cardiac issues (25%), postoperative nausea and vomiting (25%), and mortality (25%) were observed. In contrast, the control group experienced similar complications: wound infection (25%), anastomotic leak (0%), urinary/sexual dysfunction (25%),

stoma complications (33.33%), chest infection (16.67%), cardiac issues (16.67%), postoperative nausea and vomiting (16.67%), and mortality (16.67%). Significant differences were noted in wound infections (p = 0.019), which were higher in the control group. Overall, the multimodal approach showed varying rates of complications compared to standard care across different surgical procedures, highlighting potential benefits in reducing specific postoperative complications like wound infections (Table 2).

Table 1: Post operative parameters distribution in study groups.

Post op parameters	Multimodal group (n=14) Mean (2SD) days	Control group (n=16) Mean (2SD) days	P value
NG removal	1.35 (1.99)	2.06 (1.54)	0.038
Post op mobilization	1.0 (0.78)	1.68 (1.40)	0.003
Bowel sounds	1.92 (0.95)	2.64 (1.20)	0.001
Flatus	2.42 (1.02)	3.31 (1.40)	0.001
Motion	2.78 (1.78)	4.0 (2.42)	0.004
Oral feeding	2.21 (1.73)	3.06 (2.07)	0.021
Normal/solid diet	3.85 (1.32)	4.81 (2.09)	0.007
Urine catheterization	2.71 (1.22)	3.37 (2.05)	0.044
Fluid restriction	2.42 (1.09)	3.65 (1.07)	0.001
Hospital stays	6.64 (1.68)	8.25 (3.04)	0.002

*NG-nasogastric tube, op-operative, n=number of patients, SD=standard deviation

Table 2: Postoperative complications distribution in study groups.

Complications	Multimodal group (n=14)						Control group(n=16)						P value
	AR n=4		APR n=4		Hemi colectomy n=6		AR n=4		APR n=6		Hemi colectomy n=6		
	N	%	N	%	N	%	N	%	N	%	N	%	
Wound infection	1	25	1	25	1	16.67	1	25	2	33.33	2	33.33	0.019
Anastomotic leak	1	25	0	0	0	0	1	25	0	0	1	16.67	
Urinary/sexual dysfunction	0	0	2	50	0	0	1	25	3	50	0	0	
Stoma complication	0	0	1	25	0	0	0	0	2	33.33	0	0	
Chest infection	1	25	0	0	1	16.67	2	50	1	16.67	1	16.67	
Cardiac	1	25	1	25	0	0	2	50	1	16.67	0	0	
PONV	1	25	0	0	2	33.33	2	50	1	16.67	1	16.67	
Mortality	1	25	0	0	0	0	1	25	0	0	1	16.67	

*PONV-post operative nausea and vomiting, AR-anterior resection, APR-abdominal perineal resection, %-percentages

DISCUSSION

Anderson et al employed preoperative counseling, no bowel preparation, preoperative feeding, no fluid restriction, minimal invasive incision, NG tube removal, no use of drain, postoperative mobilization, postoperative feeding, no routine urine catheter, no systemic morphine, and antibiotic prophylaxis.[6] Delney et al utilized preoperative counseling, bowel preparation, no preoperative feeding, fluid restriction, no minimal invasive incision, NG tube removal, no use of drain, no routine postoperative mobilization, postoperative feeding, routine urine catheter, systemic morphine, and antibiotic prophylaxis.[8] Gatt et al incorporated preoperative counseling, no bowel preparation, preoperative feeding, no fluid restriction, minimal invasive incision, NG tube removal, no use of drain, postoperative mobilization, postoperative feeding, no routine urine catheter, no systemic morphine, and antibiotic prophylaxis.[10] Khoo et al adopted preoperative counseling, bowel preparation, no preoperative feeding, no fluid restriction, no minimal invasive incision, NG tube removal, no use of drain, no routine postoperative mobilization, postoperative feeding, routine urine catheter, no systemic morphine, and no antibiotic prophylaxis.[13] The present study includes preoperative counseling, bowel preparation, preoperative feeding, fluid restriction, minimal invasive incision, NG tube removal, no use of drain, no routine postoperative mobilization, postoperative feeding, routine urine catheter, no systemic morphine, and antibiotic prophylaxis (Table 3).

Anderson ADG's study included 14 patients in the treatment group (MG) and 11 in the control group (CG), with a mean hospital stay of 4 days (MG) and 7 days (CG). Mortality was observed only in the CG at 9%, while readmission rates were negligible in both groups. Delney CP's, RCT involved 31 patients in MG and 33 in CG, showing longer hospital stays in both groups: 5.4 days (MG) and 7.1 days (CG).[8] Specific mortality rates were not detailed, but readmission rates were noted at 10% in MG and 18% in CG. Gatt et al trial with 19 MG and 20 CG patients reported a mean hospital stay of 6.6 days (MG) and 9 days (CG), with mortality only in MG at 5% and a 20% readmission rate in CG, contrasting with Khoo CK's 2007 RCT, which registered hospital stays of 5 days (MG) and 7 days (Table 4).[10,13]

Table 3: Comparison of multimodal perioperative protocol in various randomized control studies.

Study	PC	Bowel preparation	PF	Fluid restriction	MII	NG removal	No use of drain	PM	Post operative feeding	Urine catheter	Systemic use of MR	AP
Anderson et al [6]	+	–	+	–	+	+	+	+	+	–	–	+
Delney et al[8]	+	+	–	+	–	+	–	+	+	+	+	–
Gatt et al[10]	+	–	+	–	+	+	+	+	+	–	–	+
Khoo et al[13]	+	+	–	–	–	+	–	+	+	–	–	–
Present study	+	+	+	+	+	+	–	+	+	+	–	+

PC- Preoperative counselling, PF-Preoperative Feeding, MII-Minimal invasive incision, PM-Postoperative mobilization, MR-Morphine, AP-Antibiotic prophylaxis

Table 4: This table presents results from several randomized controlled trials (RCTs) conducted over different years and designs and compared with the present study.

Study	Year	Design	No. of patients		Hospital stays (days) Mean (2SD)		Mortality %		Readmission %	
			MG (N)	CG (N)	MG (%)	CG (%)	MG	CG	MG	CG
Anderson et al[6]	2003	RCT	14	11	4 (1.8)	7 (2.1)	0	9	0	0
Delney et al[8]	2003	RCT	31	33	5.4 (2.5)	7.1 (4.8)	-	-	10	18
Gatt et al[10]	2005	RCT	19	20	6.6 (4.4)	9 (4.6)	5	0	5	20
Khoo et al[13]	2007	RCT	35	35	5 (8.5)	7 (14.35)	0	6	9	3
Present study	2017	RCT	14	16	6.64 (1.68)	8.25 (3.04)	7.14	12.5	14.28	25

*MG-Multimodal group, CG-control group, RCT-randomized control trial

In line with Arenal JJ et al.'s findings, we found that the mean duration of bowel sounds (1.92±0.95 vs. 2.64±1.20), motion (2.78±1.78 vs. 4.0±2.42) and tolerance to a normal diet (3.85±1.32 vs. 4.81±2.09) days was significantly higher in the multimodal and control groups, respectively.[1] Bowel movements (1.7±0.89 vs. 3.27±1.3), defecation (3.4±0.77 vs. 4.38±1.18), and time of solid diet tolerance (2.48±0.85 vs. 4.77±1.81) (Table 1).

The study groups experienced a significant increase in the mean duration of nasogastric removal (1.35±1.99 vs. 2.06±1.54) and flatus (2.42±1.02 vs. 3.31±1.40) days, which is comparable to the findings of Reissman et al, who concluded that there was no significant difference in the rate of vomiting (21% vs. 14%), nasogastric tube reinsertion (11% vs. 10%), and length of ileus (3.8±0.1 days vs. 4.1±0.1 days) (Table 1, Table 3).[23]

Early feeding days are similar to those reported by Anderson et al (2.21±1.73 vs. 3.06±2.07) found that patients in the optimization group (48 versus 76 h; p<0.001) tolerated a standard hospital diet substantially earlier than controls.[6]

The length of hospital stay was 6.64±1.68 days compared to 8.25±3.04 days, which is consistent with the findings of Anderson et al, (4±1.8 vs 7±2.1d, p=0.002). p=0.02, Delaney et al (5.4 vs. 7.1 days) (6.6 ±4.4 vs. 9 ±4.6d, p=0.027), Gatt et al 5 days compared to 7 days; p<0.001, Khoo et al Maximum hospitalization was reported in Khoo et al, and minimal hospitalization was found in Anderson et al, Yang et al, (6.0±1.0 vs 11.7±3.8 d, p<0.001) (Table 4).[6,8,10,13,17]

The average length of catheterization was 2.71±1.22 compared to 3.37±2.05, which is consistent with the findings of Gatt et al who found that the length of catheterization (p = 0.022) was significant.[10] Comparable intravenous fluid restriction means (2.42±1.22 vs. 3.37±2.05) litre. The median total intravenous fluid consumption in the restricted group was 4.50 (4.00-5.62) litre, while the conventional group's intake was 8.75

(8.00-9.80) litre (p<0.001), according to Mackay et al (Table 3).[20]

In line with Brandstrup et al, we found that the restricted intravenous fluid regimen significantly decreased postoperative complications by intention-to-treat (33% versus 51%, p=0.013) and per-protocol (30% versus 56%, p=0.003) analyses (Table 3).[21] Overall complication in our study was 13.40% vs. 20.31% p=0.0019) in the multimodal and control groups, respectively (Table 2).

Significant reductions were observed in the percentages of tissue-healing problems (16% against 31%, p=0.04) and cardiovascular issues (7% versus 24%, p=0.007). According to Noblett et al, there were significant postoperative problems in 2 versus 15% of cases (p=0·043) (Table 2).[24] Our series' computed readmission rate (14.28 vs. 25%, p=0.029) is comparable to that of Christensen et al, who found that the readmission rate for patients in the fast-track group was 15% and for those in the control group, 16% (Table 4).[19]

According to Gustafsson et al, readmission rates were considerably lower in cases where ERAS adherence was high (>90%) as opposed to low (<50%).[22] Our study's mortality results were 7.5% in the multimodal group and 12.5% in the control group, respectively (Figure 2). These results are consistent with those of Anderson et al, (0% vs. 9%), Gatt et al (5% vs. 0%), and Khoo et al (0% vs. 6%) (Table 4).[6,10,13]

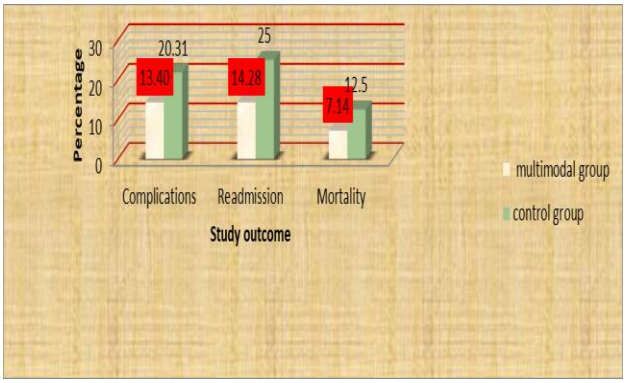

Figure 2: Postoperative complications distribution in study groups.

Our study has limitations, including a small sample size and a focus on a single governmental tertiary care center in eastern Rajasthan. It is unclear if the results can be replicated in other health care settings in India. Therefore, multi-centric trials with a diverse population from across India are recommended for validation.

CONCLUSION

For patients following elective colorectal cancer resection, the application of a multimodal recovery program greatly enhanced results. This study shows shorter hospital stays, quicker restoration of bodily functions, and a quicker return to independent status. There is no rise in postoperative complications.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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