

The Effect of Critical Pathway Care in Patients With Colorectal Cancer, Randomized Control Trials

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Abstract- Colorectal cancer and its treatment have short-term and long-term side effects for patients. One of the factors affecting these side effects is the nursing care method. This study was conducted to determine the effect of care based on the critical pathway on the duration of hospitalization, complications of the disease, and satisfaction with nursing care in patients with colorectal cancer. In a cluster-randomized controlled trial study, 70 patients with colorectal cancer were randomly selected from two hospitals of OMID (N=35) and GHAEM (N=35) in Mashhad, Iran. They were assigned to intervention and control groups. The data were collected using a characteristic of patients, and satisfaction questioner, a checklist of patient status and nursing performance, and analyzed by SPSS software version 18. There was a significant difference in the mean of satisfaction of patients from nursing care and length of hospital stay between pathway and routine care group ($P < 0.001$). There were no significant differences between pathway and routine for the postoperative complications after 12 weeks of follow-up. Our study indicates that critical pathway care can increase the satisfaction of patients and decrease the duration of hospitalization. Future studies should investigate how to increase other clinical outcomes in the oncology wards.

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Introduction

Cancer is predicted to be the first and most important cause of death among humans in 2030 (1). One of the most important types of cancer worldwide is colorectal cancer, which is the most common gastrointestinal tract cancer (2,3). Surgery is considered as one of the main and most common treatment methods for patients with colorectal cancer. However, due to the nature of colorectal cancer surgery, it is associated with many complications such as abscess, fistula, and wound infection. Among various surgical procedures, colorectal surgery has been associated with the highest rate of wound infection (4). These complications can lead to the increased length of hospital stay of the patients and incur considerable costs on the patient's family as well as the health system (5). The postoperative mortality rate is still reported to be high, which is mainly due to the increased

length of hospital stay (6). Length of hospital stay is one of the determinant factors of hospital costs, which is used as a care quality indicator (7,8). A previous study founded that the critical path method was effective in reducing the length of hospital stay and referring patients to the hospital (9). Documents confirm that critical pathway care has lower complications and mortality after surgery for patients (10). A study showed that patients who underwent gastrectomy had a shorter length of hospital stay with critical pathway care (11). Another indicator of the quality of care is the concept of patient satisfaction (12). Some studies reported that the quality of hospital services has a significant impact on patients' satisfaction (13-15). The use of a critical pathway is aimed to standardize patient management as well as improving the quality and efficiency of patient care (11,16). One of the most important issues currently considered in policy-making to improve patient satisfaction is the issue of

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healthcare services (17,18). Therefore, nursing care should be implemented more effectively. The present study is aimed to investigate the effect of critical pathway care on the length of hospital stay, complications of disease after surgical, and satisfaction of nursing care in patients with colorectal cancer.

Materials and Methods

This randomized controlled trial was conducted in educational research hospitals in Mashhad, Iran. In this study, two hospitals (HAEM and OMID hospitals) were purposive sampling selected. Then, from each of the hospitals, 38 patients were randomly selected from eligible patients. For random allocation, a box was used containing cards with the number of patients on which the words A or B were written, and each patient removed a card from the box. The intervention group and control group were assessed post-intervention, and after 12 weeks of follow-up (Figure 1).

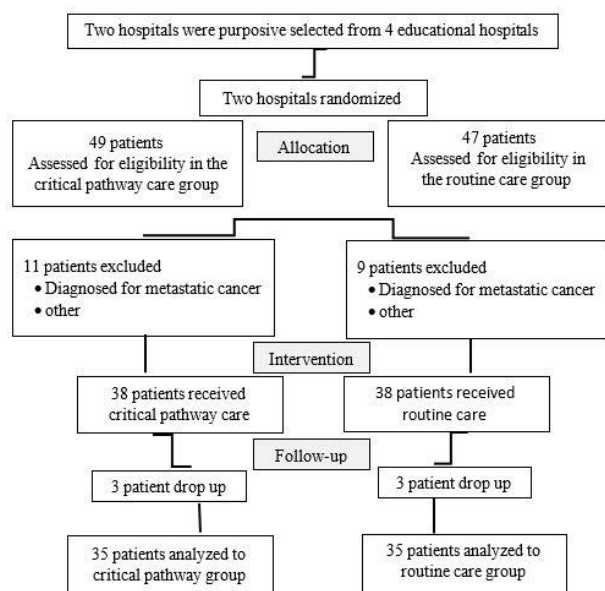


Figure 1. Follow-chart of randomized controlled trial

The most important include criteria: 1. detection of colorectal cancer based on cytology 2. Non-metastatic Colorectal cancer. 3- there is no history of previous surgery on colon or rectum 4-age between 20 and 70 years. Exclusion criteria included: 1- Discharge or transfer to other hospitals with patient consent 2- Laparoscopic surgery.

In this study, the sample size was determined based on pilot study data and mean comparison formula. A pilot study was carried out for 3 weeks' follow-up. In the pilot study, eighteen patients (10 patients in the control group, and 8 patients in the intervention group) were selected from two hospitals except for

the intervention and control groups. Mean, and the standard deviation was then determined for each of the variables of the length of stay in the hospital, patient satisfaction, and complications after surgery. The sample size was estimated based on the score of each index individually. The highest sample size was estimated based on the mean and standard deviation of patients' satisfaction with nurses' performance. The minimum sample size for each group was 29 patients. To ensure the adequacy of sample size and to consider the probability of sample loss, 38 individuals were assigned to each group.

The tool used in this research included four parts: 1- Personal information questionnaire with 19 questions based on the latest scientific resources, 2- Critical path-way care nursing Performance Checklist, 3- Checklist to determine the duration of stay in the hospital, and postoperative complications. The data from this section was extracted from patient records. Length of stay in hospital after the intervention and surgical complications after 6 months follow up were assessed. 4- Questionnaire of satisfaction of nurses' performance. The patient satisfaction questionnaire consisted of 30 questions that were abstained from PSQ3 and PSQ18. The patient satisfaction questionnaire was evaluated in the areas of general satisfaction, communication, interpersonal relationship patterns, financial contexts, time spent on patient care. This questionnaire was completed by the patients after the intervention.

The validity of these tools was done by 10 faculty members and experienced researchers. The reliability of the questionnaire of satisfaction was performed on 10 people in the study population, which was confirmed by Cronbach's alpha of 0.95. To determine the reliability of the postoperative complications checklist, the observational equivalence reliability was used. This checklist was completed simultaneously by a researcher, and a nursing graduate and its correlation coefficient were estimated to be $r=0.80$.

In this study, the intervention was conducted in four-stage for the experimental group. During the intervention, the critical pathway care method was used to care for patients in the experimental group. The control group was cared for according to the current practice of the hospital. The educational workshop was implemented based on the critical pathway care protocol to improve nurses' skills to provide care services to hospitalized patients. The length of the intervention was equal to the days of hospitalization (45 days). After the order of discharge by the physician, the required information was extracted from the patient's records, and the patient completed the questionnaire of satisfaction of nurses' performance with the presence of the researcher. The intervention and control group was followed up after 12 weeks to evaluate postoperative complications. The details of this intervention are summarized in Table 1.

Table 1. Stages of critical pathway care intervention for colorectal cancer Patients in the oncology wards

Stage of intervention	Purpose	Procedures	Method
Pre-intervention First stage (120 min)	Explanation of intervention objectives for manger	Coordinating with the manager and supervisor of the hospitals	Face to Face interaction
Pre-intervention Second stage (180 min)	Explanation of intervention objectives for nurses. Training nurses on the nature of the intervention and its process.	For all nurses working in the surgical wards, the benefits and the critical pathway care process were described. Practice to care based on critical pathway. Delivering a prototype protocol to nurses for study.	Lecture, Workshop
Intervention The third stage	Implementation of care protocol based on critical pathway method.	Suitable change in nursing care based on critical pathway care	care is planned and implemented as separate day-to-day or hour-to-hour units in accordance with the expected length of hospital stay of the patient
Post-intervention The fourth stage	Obtain the results of the intervention. To asses effect of intervention.	To collect from patients' records and completed checklists and questionnaire.	patient records and questionnaire and checklist

Statistical methods

Data were analyzed by the Statistical Package for Social Sciences software (SPSS 18, Chicago, Illinois). After collecting the data, they were first encoded and then analyzed using descriptive and analytic statistics. In this study, a confidence coefficient of 95% and the test power of 80% were considered, and in all tests, a significance level was 0.05. Initially, the normality of the quantitative variables was assessed. To describe the characteristics of the subjects, descriptive statistics, including central tendency and dispersion (mean and standard deviation) and frequency distribution, were used. Chi-square test and exact x2 tests were used to determine the homogeneity of variables. An independent t-test was used to compare the difference within groups.

The ethics committee of Mashhad University of Medical Sciences with code IR.MUMS.REC 98.20241 approved this clinical trial (IRCT2013073014225N1).

Results

Findings showed that in both routine care and critical pathway care groups, 57.2% of the participants (20 individuals) were male. In this study, in the intervention group, 2 patients were excluded from the study due to the deviation of more than 40% of nurses the form-critical path-way care checklist and one person due to discharge with personal consent. In the control group, one person due to death and two persons due to discharge with personal consent were excluded. At the end intervention, 35 patients remained in each group. The result indicated homogeneity in sociodemographic variables between two groups at the baseline. According to the Chi-square test results, the two groups exhibited no significant difference between women and men. The mean age of the critical pathway and

routine care groups was equal to 54.2 ± 2.7 and 53.6 ± 2.7 years, respectively. The mean of age did not differ between groups ($t=0.21$, $df=68$, $P=0.840$). The Chi-square test indicated the homogeneity of both groups regarding the insurance status (Table 2). Furthermore, no differences were indicated regarding medical factors between groups at the baseline.

According to the results, both groups exhibited no significant difference regarding the status of cancer stage, type of cancer, chemotherapy, radiology, and ostomy. The majority of the participants, who accounted for 68.6% of the critical pathway group and 57.1% of the routine care group, had no history of chemotherapy. The Chi-square test demonstrated the two groups were homogeneously regarded as the history of radiotherapy. Also, 72.7% of the patients in the critical pathway group and 77.1% in the routine care group had undergone colostomy surgery. The Chi-square test showed homogeneity of the two groups in terms of the type of surgery (Table 3).

Of 35 patients who cared for the critical pathway, 11 patients (31.4%) had no postoperative complications after the intervention. 9 patients (25.7%) indicated 1 postoperative complication, and 15 patients (42.8%) 2 and more than 2 postoperative complications. In the routine nursing care, 9 patients (25.7%) had no postoperative complications. 4 patients (11.4%) had 1 postoperative complication, and 22 patients (42.8%) 2 and more than 2 postoperative complications. Results of chi-square test showed that difference in the incidence of postoperative complications was not significant between two groups. ($\chi^2=2.8$, $df=1$, $P<0.089$).

The mean length of hospital stay in the critical pathway care group (6.1 ± 1.3) was less than in the routine care group (7.1 ± 6.6). In this regard, the independent t-test revealed a significant difference between the two groups ($P<0.001$, table 4). Furthermore, the mean of satisfaction with nursing care

services in the critical pathway group (143.5±17.3) was higher than the routine care group. There was a significant difference

in the mean of satisfaction of patients between two nursing care methods ($P<0.001$, Table 4).

Table 2. Sociodemographic variables in the intervention and control group

Variable	Study groups		Result of test
	Routine care n = 35 (100.0%)	Critical pathway care n = 35 (100.0%)	
Sex	Male	15 (42.8%)	X ² =0.001 df= 1 ^a P=1/000
	Female	20 (57.2%)	
Married	Married	22 (61.8%)	^b P=0/945
	Single	3 (8.8%)	
	Wife's death	5 (14.7%)	
	Divorce	5 (14.7%)	
Employed	Employee	12 (34.3%)	^b P=0/870
	Manual worker	3 (8.6%)	
	Free worker	4 (11.4%)	
	Student	1 (2.9%)	
Literacy	Unemployed housewife	13 (37.1%)	X ² =0.16 df= 1 ^a P=0/687
	Retired	2 (5.7%)	
	Less than diploma	15 (42.9%)	
	Diploma	11 (31.4%)	
Income	Undergraduate and Bachelor	8 (22.9%)	X ² =0.60 df= 1 ^a P=0.434
	Less than adequate	12 (34.3%)	
	Sufficient	23 (65.7%)	
Habitation	More than adequate	0 (0.0%)	X ² =0.07 df= 1 ^a P=0.782
	City	30 (85.7%)	
Insurance	Village	5 (14.3%)	X ² =0.57 df= 1 ^a P=0.760
	Yes	8 (22.9%)	
	No	8 (22.9%)	

^a Chi-square test, ^b Exact x² test

Table 3. Baseline medical characteristics in the intervention and control group

Variable	Study group		Result of test
	Routine care n = 35 (100.0%)	critical pathway care n = 35 (100.0%)	
Stage of disease	0	1 (2.9%)	^a P=0.535
	1	2 (5.7%)	
	2	15 (42.9%)	
	3	10 (28.6%)	
	4	7 (28.6%)	
Type of cancer	Rectum	10 (28.6%)	χ ² =0.07 ^b P=0.794 df=1
	Colon	25 (71.4%)	
Chemotherapy	Yes	15 (43.6%)	χ ² =0.979 ^b P=0.322 df=1
	No	20 (57.1%)	
Radiotherapy	Yes	18 (51.4%)	χ ² =0.23 ^b P=0.632 df=1
	No	17 (48.6%)	
Ostomy	Ilustomia	8 (22.9%)	χ ² =0.18 ^b P =0.674 df=1
	Colostomia	27 (77.1%)	

^a Exact x² test, ^b Chi-square test

Table 4. Comparison of the mean length of hospital stay and satisfaction of nursing care between the routine, critical pathway care groups after intervention

Variable	Study groups		Result of test
	Routine care mean \pm SD	critical pathway care mean \pm SD	
length of hospital stay	7.1 \pm 1.6	6.1 \pm 1.3	^a $p < 0.001$ df = 68 t = 4.5
Satisfaction of nursing care	89.17 \pm 5.1	143.17 \pm 5.2	^a $p < 0.001$ t = 13.2 df = 68

Discussion

In this study, the critical pathway method reduced the duration of hospitalization, but this effect was different in studies. One of the major strategies used by hospital managers to prevent financial losses is to reduce the patient's length of stay because it is one of the determinant factors of the hospital costs, which is used as a care quality indicator (16). Also, one of the factors affecting the length of stay in the type of nursing care method so that providing optimal care services can result in the reduced length of hospital stay (17-19).

Quality of nursing care has a significant impact on the outcomes of the disease in patients with cancer. Reducing outcomes of the disease is a key element in the quality of nursing care (20). A study indicated a further reduction in the length of hospital stay compared with that in the present study, one of the reasons for which could be the smaller sample size in the present study than the research by Kennedy. On the other hand, the length of the intervention period in Kennedy's (2009) study was about two years, while in the present study, the intervention was implemented for only 3 months. Besides, in the present study, none of the patients had malignancy, while in the study, 44% in the intervention group and 56% in the control group had malignancy, which can definitely affect the length of hospital stay (9). In another study, the patients' length of hospital stay in the critical pathway group was less than the routine care group (21). The reason for the reduced length of hospital stay in the intervention group might be the reduced unnecessary interventions, increased cooperation, and interactions of the treatment group and increased cooperation of the patient during the care procedure (22,23). Likewise, in a study, the critical pathway method resulted in the reduced length of hospital stay on pre-operative days among the patients undergoing gastrectomy surgery (11).

Our current study indicated that the critical pathway care method did not significantly reduce postoperative

complications. In this regard, there was high variation within and between studies with respect to rates and nature of complications (23). A number of these studies found that levels of postoperative complications were significantly associated with the type of nursing care (19,25,26). The principle goal of the critical pathway method is to reduce the length of hospital stay and disease complication and well as increasing the nursing care quality, and patient satisfaction in particular (27).

In this study, the average patient satisfaction level in the critical pathway group was higher than the routine care group. Another study also showed the difference in patient satisfaction between the two groups (14). The findings by Saibens *et al.*, (2010), the patient satisfaction level in the intervention group was considerably higher than that in the control group (28). Increased patient satisfaction in the intervention group can be attributed to the care process, reduced length of hospital stay, and increased patient-nurse communication. In the critical pathway care method, nurses design and implement specific considerations and techniques to achieve predetermined goals. The nurses working in this system play an important role so that providing a strategy for treatment interventions and revising different steps of the plan are among their duties (18). The treatment protocols and quality of care can lead to changes in the length of hospital stay of the patients, which will thereby affect the patients' satisfaction level (29).

Our study is limited by the absence of a researcher to monitor nurses' performance in accordance with the care protocol at all hours of the day and night in hospital wards that used the nurses' performance checklist to evaluate it.

In conclusion, this study shows that the critical pathway approach in nursing care can be a key strategy associated with positive outcomes. This approach facilitates achieving better efficiency in nursing care services. So that it can be used as an effective method and care guide in the oncology wards, our findings could be useful for explaining the modifiable mechanism to

improve nursing care for patients with colorectal cancer. Further studies to investigate other clinical outcomes in the oncology wards and the other areas of nursing practice are recommended.

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