

Effect of Development of Clinical Pathway on Post-operative complications for Colorectal Surgery Patients

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Abstract

Colorectal surgery is associated with sizeable morbidity and, for emergency surgery, considerable mortality. Clinical pathways ensure consistency in the management of patients by their streamlined approach to patient care. **Aim:** The present study aimed to determine the effect of the development of clinical pathway on post-operative complications for colorectal surgery patients. **Materials:** A quasi- experimental research design was utilized to fulfill the aim of this study. Data were collected from general surgery department and cancer institute at Aswan governorate. **Sample:** Patients admitted in general surgery department who had undergone colorectal surgery 60 patients were included in the study (30 patients in the study group and 30 patients in the control group), the mean age of the study group and control group was (52.1±6.5 & 49.7±4.7) years respectively. **Tools:** (1) Perioperative colorectal surgery patient assessment, (2) Clinical pathway variances assessment. **Conclusion:** Significant difference was observed between study and control group as regard hospital length of stay also significant difference was found between the study and control groups in relation to occurrence of postoperative complications. The study **Recommended that**, colorectal surgery clinical pathway be used rather than the traditional delivery of care

Key words: *Colorectal surgery & Clinical pathway.*

Introduction

Colorectal surgery represents a high number of patients treated at a department of gastrointestinal surgery and is not limited to cancer. It includes other non-neoplastic pathologies such as inflammatory bowel disease, diverticular disease or colonic volvulus. (Tovar,2010)

As with any major procedure, colon surgery patients may present serious or even fatal complications. The incidence of postoperative complications from colon surgery has been estimated at between 10% and 30% according to selected series. (Kehlet,2012)

Potential risks of colorectal surgery are mainly those of any major abdominal surgery, and usually occur while the patient is still in the hospital. Because of the many indications for and the various extents of colorectal or small bowel resections the rate and spectrum of complications differ. (Clavien, 2012).

The most frequent postoperative surgical complications after colorectal resections are surgical site infection, anastomotic leakage, intra-abdominal abscess, ileus and bleeding. These complications have different influences on outcome and have to be diagnosed accurately. In order to meet certain quality standards it is essential to assess postoperative complications. (Kirchhoff et al., 2010).

Clinical pathways (CPWs) aim to link evidence to practice for specific health conditions and, therefore, optimize patient outcomes and maximize clinical efficiency. For the purpose of this review CPWs are defined as structured multidisciplinary care plans which detail essential steps in the care of patients with a specific clinical problem. They support the translation of clinical guidelines into local protocols and clinical practice. Whilst clinical guidelines provide generic recommendations, clinical pathways detail the local structure, systems and time-frames to address these recommendations. (Rotter, 2010)

Aim of the study

The aim of this study was

Determine the effect of the development of clinical pathway on post-operative complications for colorectal surgery patients.

Research hypotheses

Patients on whom the clinical pathway was developed exhibit less complications than those on whom it not developed.

Significance of the study

It was the first study which made in this geographical location. As colorectal surgery carries significant morbidity and mortality, which is

associated with an enormous use of healthcare resources. So applying clinical pathway lead to better postoperative outcomes and decreases incidence of complications.

Patients & Methods

Research design:

A quasi- experimental research design was utilized to fulfill the aim of this study.

MATERIALS

Setting

The study was conducted, in general surgery department and cancer institute at Aswan Governorate

Subjects

Patients admitted in general surgery department who had undergone colorectal surgery. 60 patients were included in the study it was divided in to two groups (30 for each). The study group were 30 patients who had received the developed clinical pathway, while the control group 30 patients who received routine hospital care. The mean age of the study group and control group was (52.1+6.5 & 49.7+4.7) years respectively . The patients included were able to communicate and without vital organ failure. Patient with past history of cancer at other organ were excluded from the study.

Study tools

Two tools were used for data collection

Tool 1: Perioperative colorectal surgery patient Assessment:

This tool is an interview schedule constructed by the researcher after reviewing the related literatures to assess colorectal surgery patients at the pre, intra & post-operative period. This tool was divided into two parts to cover the following dimensions: patient profile, medical data, the patient history, current medication usage, laboratory investigations, diagnostic procedures, physical assessment, physical examination& duration of operation, occurrence of bleeding and vital signs and post-operative assessment. These data were collected through an interview; by taking history and assessment of patients. This tool includes questions in the form of multiple choice and others in the form of yes or no questions and included the following parts:

Part (I): Pre- operative colorectal surgery assessment:

This part was developed to assess the following:

In the preoperative phase

Patients profile, patient history, risk factors ,current medication usage, laboratory investigation, diagnostic studies, physical assessment, and physical examination

In the postoperative phase

Post-operative pain assessment, wound assessment, stoma assessment, post-operative surgical complications, and post-operative medical complications

Tool (2): Clinical Pathway Variances Assessment Tool:

This tool was developed by the researcher based on reviewing of the related literature (Townsend, 2009), (Rothrock 2010), (Tierney, 2011), & (Patel, 2012) it aimed to measure variations of performance. Observations of performance were checked while patient care was rendered. It was applied to the study group in a form of observational checklist related to the items of patients' care which are physical preparation, providing emotional support, colostomy care, patient teaching, pain management, activity and discharge planning and prevention of complications

Scoring system

Variations of clinical pathway performance were checked according to the researcher's observations on 2 points likert scale. The score ranged from one to three with a total score value ranging between 10-30, as follows:

- Two equal to "done adequately" if the activity followed safe, complete, accurate step and performed on time, with the required frequency.
- One equal to "not done" if the activity was not performed.

Method

Written approval

A written approval was obtained from the administrative personnel at the study settings after explanation of the purposes.

Testing of validity

Content validity was done for the six developed tools. The content validity was submitted to a 7 jury members: Five professors from Assiut Faculty of Nursing and two professors from Assiut Faculty of Medicine.

Every jury member was informed about the aim of the study; they reviewed the developed tools and after consensus necessary modifications were carried out.

Testing of reliability

The reliability of assessment tools were tested using Cornbrach's alpha as follows (r= Perioperative colorectal surgery patient assessment tool: (0.845.), &Clinical Pathway Variances observation checklist Assessment: (0.874)

Ethical Considerations

The researcher introduced himself to every patient including in the study, explained the purpose of the study. Patient's written Informed consent to participate in the study was then obtained. Every

patient was informed that anonymity, confidentiality and privacy will be assured.

Pilot study

Six patients (10%) were selected conveniently to check and ensure clarity, applicability, and feasibility of the tools and to identify the difficulties that might be faced during the application. Necessary modifications were carried out accordingly.

Data collection:

Data was collected for a period of 12 months, from May 2014 to the end of May 2015.

Development of colorectal surgery clinical pathway

Clinical pathway for colorectal carcinoma, this tool was developed by the researcher after extensive review of related literatures (Aledo, 2011) this tool was applied on the study group.

Phase one: Assessment of the Current Practice:

- Study of hospital routine as baseline for clinical pathway development:

The researcher observed nurses performance related to pre and post colorectal surgery care in oncology surgery unit for a period of one month before the establishing clinical pathway in the pre and postoperative period:

- Data collection of the control group:

Data collection started with control group who were managed according to hospital routine. Preoperative assessment of every patient in control group was done preoperatively using (Tool I part I) "Perioperative Colorectal Surgery Patient Assessment" part I "Preoperative Assessment" at general surgery department and cancer institute in the preoperative period. Subsequent using tool I part II "Post operative assessment" was utilized by the researcher daily for 4 days post-operative at general surgery department and cancer institute in order to evaluate patient's health outcomes.

Phase two: Clinical pathway development:

The researcher prepared a colorectal surgery clinical pathway template which starts with patients' profile, medical data, in addition to the clinical pathway team's role. The tool format was prepared in a matrix form that included eight vertical columns representing time intervals and seven horizontal rows representing patient's care items.

Content validity of clinical pathway was done by 7 experts in medical surgical nursing, colorectal surgery, and necessary modifications were done.

Phase three: Clinical pathway implementation and data collection of the study group:

Data collection from the study group who were subjected to the clinical pathway implemented by the researcher was carried out after completion of control group data collection.

Phase four: Clinical Pathway Evaluation Statistical Analysis

Evaluating the clinical pathway: it consisted of comparing the outcomes of both groups by using Tool one and Tool Two in relation to (postoperative pain relief, post-operative complications as anastomosis leakage paralytic ileus, respiratory complications, & length of hospital stay,

After data were collected and transferred into specially design formats, so as to be suitable for computer feeding. Data were analyzed using PC with statistical Package for Social Sciences (SPSS) version 20.

A- Descriptive statistics

- Count and percentage: Used for describing and summarizing Categorical variables
- Mean and standard deviation: Used for describing and summarizing continuous variables.

B- Analytical statistics:

- Cronbach's Alpha reliability test:

It was used to measure the reliability of the developed tools. Its maximum value is ($\alpha = 1.0$) and the minimum accepted value is ($\alpha = 0.7$); below this level the tool would be unreliable.

- Chi-square test (χ^2) and fisher exact test: used to compare between categorical variables.
- **t-test** Test: used to compare between continuous variables.
- 5% level of significant was chosen where $p \leq 0.05$ was considered significant and $p > 0.05$ was considered as non-significant.
- The data were tested for normality using the Anderson-Darling test and for homogeneity variances prior to further statistical analysis.
- **A two-tailed $p < 0.05$** was considered statistically significant. All analyses were performed with the **IBM SPSS 20.0** software.

Graphical presentations

Pie charts and bar graphs were drawn for data visualization of study and control findings using Microsoft Excel.

Results

Table(1): Frequency and percentage distribution of the study and control group as regards patient profile (n= 60).

Patient profile	Control group n=30		Study group n=30	
	N.	%	N.	%
Age, mean±SD	49.7±4.7		52.1±6.5	
Sex				
Male	18	60.0	15	50.0
Female	12	40.0	15	50.0
Educational level				
Illiterate	12	40.0	18	60.0
Reading and writing	3	10.0	3	10.0
Primary school	3	10.0	0	0.0
Preparatory school	0	0.0	3	10.0
Secondary school	12	40.0	0	0.0
University	0	0.0	6	20.0

Table(2): Assessment of preoperative potential risk factors for study and control group (n= 60).

Nutritional status	Control group n=30		Study group n=30	
	N.	%	N.	%
Under weight	15	50.0	15	50.0
Desirable	12	40.0	6	20.0
Over weight	3	10.0	9	30.0
Diabetes	6	20.0	3	10.0
Hypertension	0	0.0	3	10.0
Kidney failure	0	0.0	0	0.0
Anemia	12	40.0	9	30.0
COPD	3	10.0	0	0.0
Current medication usage				
Steroids	3	10.0	0	0.0
Chemotherapy	9	30.0	6	20.0
Radiation therapy	3	10.0	3	10.0

Table (3): Comparison between the study and control group as regards post-operative wound and stoma assessment.

	Control group N=30		Study group n=30		P. value
	N.	%	N.	%	
Wound assessment					
Pain or tenderness	18	60.0	9	30.0	0.020*
Localized swelling	15	50.0	3	10.0	0.001**
Hotness	12	40.0	-	-	0.000**
Redness	12	40.0	-	-	0.000**
Purulent discharge	9	30.0	-	-	0.001**
Delayed healing	9	30.0	-	-	0.001**
Offensive wound exudates	9	30.0	-	-	0.001**
Dehiscence	6	40.0	-	-	0.031*

	Control group N=30		Study group n=30		P. value
	N.	%	N.	%	
Stoma assessment					
Slight edema	15	50.0	15	50.0	1.000
Bleeding	3	10.0	0	0.0	0.202
Necrosis	0	0.0	0	0.0	-
Stoma retraction	6	20.0	0	0.0	0.032*
Skin irritation	6	20.0	3	10.0	0.121

N.B: - = 0

Table (4):Relation between the application of clinical pathway and post-operative paralytic ileus.

	Control group		Study group		P. value
	N.	%	N.	%	
Paralytic ileus	6	20.0	-	-	0.010**

Statistically significant difference ($p=0.01$)

Table (5): Relation between the application of clinical pathway and post-operative wound infection (n= 60).

	Control group		Study group		P. value
	N.	%	N.	%	
-Wound infection	6	20.0	-	-	0.031*

Statistically significant difference ($p<0.01$)

N.B: - = 0

Table (6): Relation between the application of clinical pathway and hospital length of stay.

	Control group		Study group		P. value
	N.	%	N.	%	
Hospital length of stay	13.7±7.4		8.8±3.1		0.001**

Statistically significant difference ($p<0.001$)

Table(1): Characteristics of patients under the study: the data reveals that the mean age of the study group was (52.1±6.5), half of them (50%) were male and more than half of them (60%) were illiterate. While in control group the mean age was (49.7±4.7), more than half of them were male (60%), (40%) were illiterate, (40%) were secondary school, (10%) were reading & writing and (10%) were primary school.

Table(2): Distribution of the study and control group regarding preoperative potential risk factors for study and control group, half of patients in both study and control groups were under weight, (20% and 40%) of both study and control groups respectively had desirable weight and there were increase in the percentage of obese patients in the study group than the control one (30% and 20%) respectively. As well, the highest percentage (30.0%) in study group have anemia and (10%) have diabetes and hypertension and in control group were (40%) of patients have anemia, (20%) have diabetes.

Table(3): Demonstrated that, more than half of patients of control group (60.0%) and (30%) of the

study group had experienced pain and tenderness and one half of the control group had localized swelling in relation to hotness, redness, purulent discharge, delayed healing, & dehiscence, the highest percentage were in the control group (40%, 40%, 30%, 30%, 30%, & 40%) and 0 % of the study group with statistical significant differences between study and control group regarding wound assessment. Considering stoma assessment half of patients of control group and study group had experienced slight edema. The data also revealed that increased percentage of bleeding, Stoma retraction, & Skin irritation were in the control group than the study one. (10%, 20%, 20%) of the control group versus (0%, 0% & 10% of the study group) with statistical significant differences between study and control group in relation to stoma retraction ($P= 0.032^*$).

Table(4): Presented significant difference between study and control group as regard paralytic ileus ($P=.010$)

Table (5): Had shown that significant difference was observed between study and control group as regard wound infection ($p=.031$)

Table (6): Revealed that significant difference was observed between study and control group as regard hospital length of stay $P= 0.001$.

Discussion

The findings of the present study revealed that there were no statistical significant differences in the basic data (patient's age & sex) between the control and study groups. While highly significant difference was observed between the study and control group related to the educational level at the beginning of the study.

Concerning gender, the present study showed that more than half the control groups were male, this finding in the line with those of **Ferlay, (2013)** who mentioned that the incidence of CRC for women is lower than that for men worldwide, although there is some geographical variation. As well, **Oberoi, (2014)** mentioned that men are known to have increased risk, higher incidence and worse prognosis for CRC than women. Men are more likely than women to develop CRC at all ages. Furthermore this finding was also agree with that of **Weige et al., 2009 & Lawrence, et al., (2007)** who found that women are less likely than men to develop cancer, as estrogen hormone reduces the incidence of cancer in women. Collectively, estrogen appears to be protective for colorectal cancer development in women.

In relation to educational level, more than half of the study group and more than one-third of the control group were illiterate. This result is consistent with **Mohammed, (2016)** who mentioned the highest percentages of patients undergoing colorectal surgery in both control and study groups were illiterate and primary education. On the other side highly educated patients represented less than one fourth of the studied group and none of the control group. This result was supported by **Chen et al., (2010)**, who mentioned that patients with higher education had high global health status. As well, **Mouw et al., (2009)**, clarified that the higher level of educational attainment had lower cancer risk. Furthermore, the present result was explained by (**Maziad, 2012, Albano, 2012 and Heleny, 2013**) as they reported that, higher education levels were strongly associated with decreased cancer incidence from lung, colorectal, breast, and prostate cancers. But the groups of people with less education have higher incidence rates of cancer. Also, they added that the result may be due to increased knowledge and perception of highly educated people about the

importance of early detection of cancer and selection of appropriate time for cancer treatment.

Considering preoperative potential risk factors, results revealed that

there were increased in the percentage of obese patients in the study group than the control one. On same line, this result agree with **Craig & Jennette, (2015)**, who reported that, one of the strongest lifestyle risk factors associated with this cancer is body mass index. The International Agency for Research on Cancer concluded that 11% of colon cancer cases were caused by obesity.

The results also revealed that more than one third of the study group and more than one fourth of the control group had anemia this result agree with **Muñoz, (2014)**, who stated that anemia is one of the most frequent extra intestinal manifestations of colorectal cancer (CRC).

As regard the relation between the application of clinical pathway and postoperative ileus results revealed increased percentage of patients who had experienced paralytic ileus during the postoperative day-1 and day-2 in the control group than the study one with significant difference between study and control group as regard paralytic ileus. This findings agree with, **Jane, (2010)** who stated that postoperative complications were significantly reduced in clinical pathway patients.

Study results also show that half patients of the control group had wound infection during the post-operative day-1 and day2 with significant difference was observed between study and control group as regard wound infection this findings come in accordance with **Ishikawa, (2014)** who mentioned that Surgical site infections (SSI) are the most common nosocomial infection in surgical patients, contributing to perioperative morbidity, prolonged postoperative hospital length of stay, and increased hospital costs. As well, **Smith et al., (2009)** clarified that surgery for colorectal cancer is associated with bacterial contamination and postoperative wound infections.

As regard hospital length of stay, results revealed that significant increased hospital length of stay in the control group than the study one with significant difference between the two group. This agrees with **Nussbaum et al., (2014)** who emphasized that hospital length of stay was shorter on patient treated with clinical pathway.

Conclusion

Implementation of clinical pathway for patients undergoing colorectal surgery exhibited significant differences in incidence of post-operative complications and hospital length of stay in patients

going through clinical pathway and those who are undergoing hospital routine care

Recommendation

- Development and application of clinical pathways in other areas of clinical specialties.
- Evaluate the effect of development and application of clinical pathways in colorectal cancer patient undergoing various treatment modalities as chemotherapy or radiotherapy.
- Study the staff satisfaction and cost effectiveness after implementation of the clinical pathway.

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