

Effectiveness of Nursing Care Protocol on Preventing and Managing Radiotherapy Induced Oral and GIT Toxicity in Cancer Patients.

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Abstract: Gastrointestinal side effects are the most common side effects of radiation therapy which limit the deliverable intensity of radiotherapy, and might affect the long term health-related quality of life of the patient. Efforts to manage GIT side effects in cancer patients should focus on patient education. Therefore, the aim of the present study was to evaluate the effectiveness of nursing care protocol on preventing and managing radiotherapy induced oral and GIT toxicity (nausea, vomiting, diarrhea and oral mucositis) in cancer patients. **Methods:** Quasi-experimental (case control) research design was conducted in the Clinical Oncology and Nuclear Medicine Department at Main Mansoura University Hospital (inpatient and outpatient). **Sample:** The data were collected from 200 adult patients of both sexes randomized selected who corresponded to inclusion criteria and divided into two groups. **Tools:** two tools were used; A structured Interview questionnaire, and assessment scales (nausea assessment scale, vomiting assessment scale, diarrhea assessment scale and WHO oral mucositis scale). **Result:** The results indicate increased total knowledge score for patients at posttest and follow up after implementation of the protocol of nursing care. There was a highly statistically significant relation between severity and incidence of different scales among the patients of control and study group. **Conclusion:** The implementation of nursing care protocol has a positive effect on the studied patients' total knowledge scores and decrease incidence and severity of oral GIT toxicity in the study group and control group than follow up test.

Keywords: nursing care protocol, oral and GIT toxicity, Cancer, Radiotherapy

I. Introduction

Gastrointestinal toxicities (GIT), including oral mucositis, nausea, vomiting, dyspepsia, diarrhea, and constipation are common adverse events of antineoplastic treatments. These side effects are frequently associated with classical chemotherapy drugs, although their rate of occurrence may vary according to treatment schedule [1]. Of all toxicities associated with cancer therapy, from a patient's perspective GIT are the most bothersome and consistently challenge patients' ability to tolerate cancer care [2]. According to the National Cancer Institute's (NCI's) Common Terminology Criteria for Adverse Events, more than half of patients receiving chemotherapy and radiotherapy for colorectal cancer experienced diarrhea of grade 3 or grade 4, diarrhea is also commonly observed in patients diagnosed with carcinoid tumors, receiving radiation therapy to abdominal/pelvic fields, or undergoing bone marrow transplantation or surgical intervention of the gastrointestinal tract. [3] Diarrhea occurs in approximately 7% to 10% of cancer patients upon admission to hospice. [4] The consequences of diarrhea can be significant and life-threatening. In a large heterogeneous sample of cancer patients in various stages of treatment, the prevalence of moderate-to-severe diarrhea was 14%. [5] Nausea and vomiting are 2 of the most dreaded, unpleasant side effects of cancer treatment, but they only rarely become life-threatening. Still, nausea and vomiting can make it hard to get the nutrition your body needs. And repeated vomiting can lead to dehydration, which is a lack of fluids and minerals your body needs. Dehydration can make you not want to eat or drink anything, and if it continues, it can become a serious problem very quickly. Be sure to let your cancer [6]

Oral mucositis is a common complication of chemotherapy and radiotherapy. It begins 5-10 days after the initiation of radiotherapy and lasts 7-14 days. Radiotherapy-induced oral mucositis causes the mucosal lining of the mouth to atrophy and break down forming ulcers. Some degree of oral mucositis occurs in approximately 40% of patients who receive cancer chemotherapy. At least 75% of patients who receive myeloablative conditioning regimens (chemotherapy with or without total body irradiation) in preparation for HCT develop oral mucositis; the incidence may be even higher in children. [7]

Aim of the study

This study aimed to evaluate the effectiveness of nursing care protocol on preventing and managing radiotherapy induced oral and GIT toxicity (stomatitis, nausea, vomiting and diarrhea) in cancer patients.

Research hypothesis

1. There will be improvement in the patients' knowledge regarding GIT toxicity after implementing the nursing care protocol
2. There will be a decrease in the incidence and severity of GIT side effects

II. Materials and Method

Research design

Quasi-experimental research design was utilized in this study.

Subjects:

The study sample consisted of 200 adult patients (males and females) randomly selected.

Setting of the study

The study was carried out in oncology clinics of the Clinical Oncology and Nuclear Medicine Department at Main Mansoura University Hospital (inpatient and outpatient clinics).

The study subjects were consisted of two equally:

Group (A): study group, consisted of 100 adult patients who were followed by the nursing care protocol on radiotherapy. GIT toxicity (nausea, vomiting, diarrhea and oral mucositis)

Group (B): Control group, consisted of 100 adult patients who were followed by routine hospital care.

Inclusion Criteria

- Adult patients ranged from 20 to 65 years.
- Scheduled for receiving radiotherapy for at least one month (15 sessions).
- Free from chronic diseases such as cardiac, renal and diabetic diseases

Tools of the study

Tool I: Structured Interviewing questionnaire.

This tool was developed by the researcher after reviewing the relevant literature to assess patients' knowledge related to GIT toxicity (nausea, vomiting, diarrhea and oral mucositis) of radiotherapy. This tool was translated into Arabic language.

. This tool consisted of two parts:

Part 1: Socio-demographic data and medical data sheet.

This part included items related to patient's age, sex, level of education, occupation, marital status, duration of disease, data related to previous hospitalization, family history related to disease, diagnosis, grade of cancer, previous methods of treatment if present, type of radiotherapy used, schedule of sessions of radiotherapy, and problems (side effects) occurring during radiotherapy.

Part 2: Patient's knowledge related to GIT toxicity (nausea, vomiting, diarrhea and oral mucositis) of radiotherapy.

This tool was used to assess patient's knowledge in relation to GIT toxicity (nausea, vomiting, diarrhea and oral mucositis) of radiotherapy, and self-care measures to manage and care for nausea, vomiting, diarrhea and oral mucositis of radiotherapy.

Tool II: patients' assessment scale:

1- Nausea and vomiting assessment scale

This tool was developed by (Morrow, 1992)⁸ to assess and evaluate the severity of nausea and vomiting. This scale ranged from 0 (none) to 5 (severe)

2- Diarrhea assessment scale

This scale adopted from (National Cancer Institute, 2009)⁹. Likert-type response scale to measure the presence and severity of diarrhea. Total score ranging from 0 to 12. The total score is categorized as follows: 0-3=No diarrhea, 4-6=mild diarrhea, 7-9=moderate diarrhea and 10-12=severe diarrhea.

3- Oral toxicity scale¹⁰

This scale adopted from (WHO, 1979)¹⁰ to assess oral toxicity and the scale rating from grade 0 to grade 4 which listed as following grade (0) no side effects, (1) sore mouth no ulcers, (2) sore mouth with ulcers but able to eat normally, (3) able to eat liquids only and (4) unable to eat and drink.

4- Method

Permission to conduct the study was obtained from the Oncology and Nuclear Medicine Department administrator and head of department at Main Mansoura University Hospital. An informed oral consent was taken from the study sample before inclusion in the study, after explanation of the purpose of the study. The researcher emphasized that participation in the study was entirely voluntary; each patient had the right to refuse the participation in the study. At any time of the study, the patient has the right to withdraw from the

study. A pilot study was carried out on 10% of the subjects (20 patients) undergoing radiotherapy for testing feasibility and applicability of the tools. The needed corrections, modifications, omission and addition were made. Patients included in the pilot study were excluded from the study patients. Patients of control group followed a routine hospital care while patients in study group followed the nursing care protocol to radiotherapy side effects along with routine hospital care. Nursing care protocol was conducted for the study group patients before their starting in radiotherapy sessions. The data for the two groups (study and control) were collected throughout three phases of assessment and scheduled as following: The first phase was done prior to conducting the nursing care protocol, the second phase was done immediately post implementing nursing care protocol, and the third phase was done immediately after finishing the course of radiotherapy sessions. Implementation of nursing care protocol, the implementation phase was done through five major sessions; each session was conducted for 20 patients sometimes for each patient individually according to his condition, one session per day; the time allowed varies between 30-60 minutes. Implementation of oral care protocol, the implementation phase was done through five major sessions; each session was conducted for 5 to 10 patients sometimes for each patient individually according to his condition, one session per day; the time allowed varies between 20-50 minutes. All sessions were ended before second phase of assessment. The data were collected at March 2016 and ended at August 2016

III. Results

Table (1): indicate that 50% of patients in the study group and 45% of studied patients in the control group were at age group 50 years, 58% of patients in the study group and 55% of patients in the control group were female, the rural residence was prevailing among 62% and 58% of patients in the study and control groups respectively, 40% of patients in the study group and 35% of patients in control group were secondary school education while 8% of patients in the study and 10% of patients in the control group were read and write, 83% of patients in the study group and 82% of patients in control group were married and 50% of patients in the study group and 53% of patients in the control group were house wife.

Table (2): shows that the majority of studied patients in the study and control group (98% & 97%) had 25 sessions of radiotherapy, and regarding the site of radiotherapy, 40% of patients in the study group and 39% of patients in the control group were chest wall radiation while 17% of patients in the study group and 15% of patients in control group concerning head and neck radiation. Regarding the previous treatment, 31% of patients in the study group had previous surgical treatment and 35% of patients in the control group had no previous treatment, while 15% of patients in the study group and 5% of patients in the control group treated previously with chemotherapy.

Table (3): shows that, there were highly statistically significant relation between patients' knowledge scores regarding the care of oral and GIT toxicity and the protocol of nursing care implementation among patients in both the study group and control group post and follow up tests ($p \leq 0.001$), while there were no statistically significant among patients in both the control and the study group pretest.

Table (4): show impact of relaxation technique and diet modifications on incidence of nausea, vomiting and diarrhea radiotherapy side effect of the study and control groups at pre, post, and follow up test which illustrates that, all patients in both study and control group had no incidence of nausea, vomiting and diarrhea pre-test according to nausea, vomiting and diarrhea assessment scale with no statistical significant differences, while at post test, there were decrease in mean score follow up among patients in the study group and control group regarding incidence of nausea and vomiting after implementing the diet modification and relaxation technique with highly statistically significant difference ($p \leq 0.001$). Concerning to incidence of vomiting and diarrhea at post and follow up among patients in control group showed decreased in their mean scores and there was highly statistically significant difference follow up where $p \leq 0.001$.

Figure (1): Shows severity of diarrhea as radiotherapy side effect of the study and control groups at the end of study (follow up) which illustrates that, 16% percent of the study group have diarrhea less than 4 times per day, compared to 16% have > 4-6/day diarrhea frequency, and 13% more than 7 / day diarrhea frequency in the control group.

Table (5): shows impact of oral care on incidence of stomatitis as radiotherapy side effect of the study and control groups at pre, post, and follow up test which illustrates that, there were highly statistically significant difference between the study and control groups as regards incidence of stomatitis at post, and follow up ($p \leq 0.001^{**}$). Furthermore, the results revealed increased in mean score of stomatitis for the patient in the control

group at post, and follow up. On the other hand there were no statistical significant differences between study and control groups pre implementing oral care.

Figure (2): Severity of stomatitis as radiotherapy side effect of the study and control groups at the end of study (follow up) which indicates that, 92% of study group free from stomatitis compare to 19% suffering from stomatitis in the control group at follow up .

Discussion

Radiotherapy -induced gastrointestinal toxicities not only are a common problem in cancer patients but they often are clinically significant with potentially negative effects on both patient's outcome and cancer care costs. So, this study aimed to evaluate the effectiveness of nursing care protocol on preventing and managing radiotherapy induced oral and GIT toxicity in cancer patients.

The present study findings revealed that, about one half of the study patients were in the age group of 50 years and more. This in agreement with, American Cancer Society (2011)¹¹ which reported that, most cases occur in adults who are middle aged or older, about 78% of all cancers are diagnosed in persons 55 years of age and older. Females constituted about more than half of the study patients, this may be related to the high incidence of breast cancer among cancer patients according to Mansoura University hospital statistical report 2011. This finding is contradicted by Brenner et al. (2009)¹² who agreed with American Cancer Society (2009)¹³ that, the incidence of cancer is higher in men than in women. Concerning to the level of education the present study revealed that two fifths of patients in the study group were secondary level of education, this is may be related to the fact that, majority of the study subject came from rural area with low socioeconomic level, half of patients were house wife and interested in manual and farmer work.

Incidence of breast cancer and gastrointestinal cancer were higher in the Egyptian population (National Cancer Institution, 2011)¹⁴. This goes with the finding of the present study where two fifths of the patients had chest wall site cancer and about one fifth had GIT cancer.

The present study revealed that there was a highly statistical significant improvement in the total knowledge score of the patients in the study and control group after applying nursing care protocol sessions in comparing with the control group. This is supported by the study done by Caroline Häggmark et al. (2011)¹⁵ who found that, knowledge scores were consistently increased for the nursing consultation group. Also this study shown that, the patient information was a significant important in preparing the patients for the procedure of receiving radiation therapy.

Regarding the patient knowledge related to side effects of radiotherapy and measures to overcome, the present study clarifies a highly improvement in patient knowledge with a highly statistical significant difference between the study group and the control group after implementation of nursing care protocol sessions. These go in line with Glanz et al. (2008)¹⁶ who noted that education plays a vital role in helping patients and their families to become involved in their cancer treatment and dealing with side effects. On the same line McPherson et al. (2011) reported that, cancer patients who have an educational session with oncology nurses in advance of the initiation of treatment will learn how to reduce the risk of and manage adverse effects and maximize well-being. Helping patients to manage their side effects reduces adverse events and recognize the need for urgent or inpatient care.

The present study found a decrease in the incidence of GIT mean score in the study group with a highly statistical significant difference between the study group who follow nursing care protocol as relaxation technique, and patient education about diet modification. This result goes in line with (Roe and Lennan, 2014)¹⁷ who found that nursing education play an important role in the monitoring, controlling and preventing the GIT side effects of radiotherapy. The result is agree with the study done by Shebl, Ismael and Hassanein (2014)¹⁸ who proved that there were decreased incidence and severity of GIT side effects at post and follow up tests was found.

The present revealed that, decreased incidence and severity of stomatitis radiotherapy side effects for the study group at post, and follow up tests than control group. In agreement with this result, Ashing-giwa (2006)¹⁹ who confirms that, lower level of knowledge resulting in lack of awareness about cancer and available treatment, while knowable patient are more aware about disease, side effects, and better access to care and its benefits. Also Padberg & Padberg (2009)²⁰ who emphasized that, cancer patient with less knowledge need good assistance and more detailed explanation of their options to overcome disease stressed situation. On the other hand Johnson & Blumberg (2008)²¹ who stressed that, lack of information may lead to increased severity of side effects, anxiety, and distress, also may impact negatively on the patient's satisfaction and may influence a patient's treatment choices and outcome.

The present study shows that, patients of control group appeared to be affected by stomatitis more than the study group who maintain the routine oral care. This is may be related to deposit of food, debris on teeth and left mouth at great risk for dryness, infection and bad mouth odor, also, most of the patients did not give an attention to oral care or oral hygiene and patients give their attention to physical disease and do not go to dentist even with a problem in teeth due to decrease level of awareness about oral hygiene and its importance. Others, for reasons of physical or cognitive disability, or due to illness or advanced age, so these peoples will need assistance in carrying out dental and periodontal care to protect against gum disease, dental caries and risk for stomatitis.

IV. Conclusion

Based on the present study findings, it can be concluded that a marked gap in the knowledge of cancer patient receive radiotherapy. In addition, the implementation of nursing care protocol has a positive effect on the studied patients' total knowledge scores and decrease incidence and severity of oral and GIT toxicity in the study group and control group than follow up test.

V. Recommendations

Based on the results of the present study, the following recommendations are suggested:

- 1- Cancer patients should be given a written instruction plan for their radiotherapy steps and self- management measures to radiotherapy.
- 2- Nursing management protocol should be integrated within the plan of care for cancer patients going to radiotherapy. This protocol should emphasize patients' education about the disease process, treatment modalities, behavior and life style modification, different relaxation techniques, psychological support, financial support, and coping behaviors that the patients can integrate into their lifestyle.
- 3- Development of cancer education center in nuclear- medicine department is essential to provide inpatient and outpatient nursing management protocol for cancer patients receive different type of treatment modalities.
- 1- Developed illustrated booklet should be available and distributed for each cancer patient admitted to the hospital.

Further researches:

More researches are needed to investigate the long-term effect of such educational intervention.

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Table (1): Distribution of studied patients (study and control) according to socio-demographic characteristics

Socio-demographicData	Groups	
	Study N=100 N&%	Control N=100 N&%
Age group		
20-	4	9
30-	22	18
40-	24	28
50-	50	45
Gender		
Male	42	45
Female	58	55
Residence		
Rural	62	58
Urban	38	42
Educational level		
Illiterate	25	22
Read & write	8	10
Secondary	40	35
University	27	33
Marital status		
Single	10	12
Married	83	82
Widow	7	6
Divorced	0.0	0.0
Occupation		
Employee	22	14
Student	4	6
Worker	18	19
Farmer	4	6
House wife	50	53
Others	2	2

Table (2): distribution of health relevant data among study and control group

Health relevant data	GROUPS	
	Study group	Control group

	N= 100	N= 100
Sessions No		
15	2	3
25	98	97
Site of radiotherapy		
Head & neck	17	15
Chest	40	39
Abdominal	20	16
pelvic	23	30
Previous treatment		
None	30	35
Chemotherapy	15	5
Surgical	31	28
others	24	32

Table (3): Mean score, standard deviation and test of significance of patient's knowledge regarding the care of radiotherapy induced oral and GIT toxicity (stomatitis, nausea, vomiting, and diarrhea) among the study and control groups after protocol of nursing care implementation.

oral and GIT toxicity	GROUPS			
	Study group Mean± SD	Control group Mean± SD	t	P
Stomatitis				
Pre test	1.01± 0.38	0.92 ± 0.37	1.698	>0.05
Post test	9.8±1.08	1.64±0.99	55.626	≤ 0.001**
Follow up	9.42±1.30	1.7±1.1	44.468	≤ 0.001**
Nausea & vomiting				
Pre test	0.98±0.79	0.87±0.46	0.218	>0.05
Post test	7.6±0.80	1.35±0.68	59.092	≤ 0.001**
Follow up 1	7.18±1.40	1.71±1.26	28.954	≤ 0.001**
Diarrhea				
Pre test	1.15±0.77	1.04 ± 0.66	0.320	<0.05
Post test	11.0±1.57	1.55±0.93	51.701	≤ 0.001**
Follow up 1	10.26±2.26	1.82±1.25	32.639	≤ 0.001**

X2: chi- square test Significant (p< 0.05)** High significant (p<0.01*)

Table (4): Impact of relaxation technique and diet modifications on incidence of nausea, vomiting and diarrhea radiotherapy side effect among the study and control groups at pre, post, and follow up test.

	GROUPS			
	Study group Mean± SD	Control group Mean± SD	t	P
Nausea assessment scale				
Pre test- 1 st assessment	0.0±0.0	0.0±0.0	----	-----
Post test– 2 nd assessment	0.0±0.0	0.06±0.23	2.514	> 0.05
Follow up - 3 rd assessment	0.02±0.14	0.36±0.48	6.766	≤ 0.001**
Vomiting assessment scale				
Pre test- 1 st assessment	0.0±0.0	0.0±0.0	----	----
Post test – 2 nd assessment	0.0±0.0	0.03±0.17	2.514	< 0.05
Follow up - 3 rd assessment	0.0±0.0	0.11±0.31	6.766	≤ 0.001**
Diarrheaassessment scale				
Pre test- 1 st assessment	0.0±0.0	0.0±0.0	-----	-----
Post test – 2 nd assessment	0.0±0.0	0.06±0.23	2.514	< 0.05
Follow up - 3 rd assessment	0.0±0.0	0.30±0.66	6.766	≤ 0.001**

Figure (1): Severity of diarrhea as radiotherapy side effect of the study and control groups at the end of study (follow up).

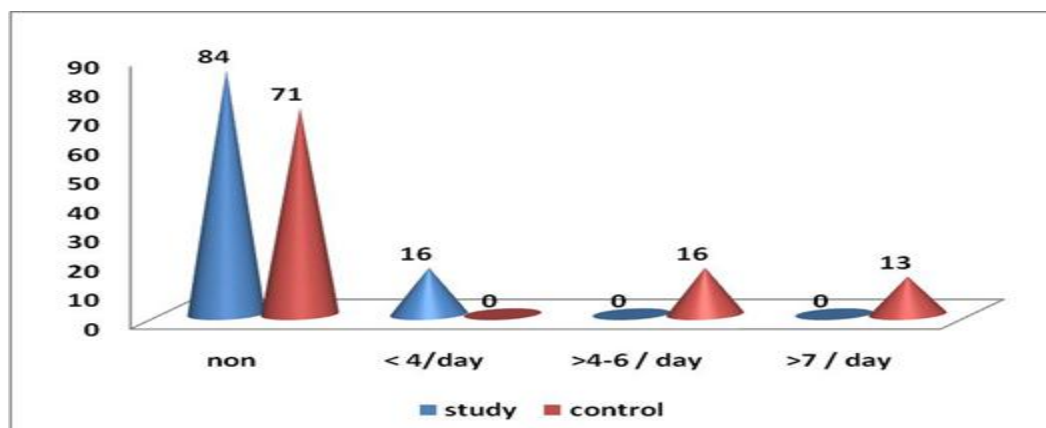


Table (5): Impact of

oral care on incidence of stomatitis as radiotherapy side effect among the study and control groups at pre, post, and follow up test.

Oral toxicity scale	GROUPS		t	P
	Study group Mean± SD	Control group Mean± SD		
Pre test- 1 st assessment	0.0±0.0	0.0±0.0	----	-----
Post test – 2 nd assessment	0.0±0.0	0.16±0.33	5.143	≤ 0.001**
Follow up - 3 rd assessment	0.02±0.14	0.36±0.48	3.766	≤ 0.001**

Figure (2): Severity of stomatitis as radiotherapy side effect of the study and control groups at the end of study (follow up).

