# Effect of an Instructional Module on Acute Side Effects of Intensity Modulated Radiotherapy for Patients with Cancer Prostate

## Soheir Mohammed Weheida, Professor

Medical Surgical Nursing, Faculty of Nursing, Alexandria University

## Zeinab Mohamed Ahmed, Assistant Lecturer

Medical Surgical Nursing, Faculty of Nursing, Alexandria University

## Laila Mohamed Abdo, Professor

Medical Surgical Nursing, Faculty of Nursing, Alexandria University

# Narges Mohamed Siam, Lecturer

Medical Surgical Nursing, Faculty of medicine, Alexandria University

## Abstract

**Background:** Over the past few decades, there have been significant advances in the delivery of radiotherapy. These include developments in treatment planning systems and linear accelerator delivery capabilities, which reduce the risk of toxicity and morbidity as intensity modulated radiotherapy (IMRT). However have certain negative acute side effects as urinary tract infection (urinary urgency, frequency and dysuria), diarrhea, severe pain in anorectal area, hemorrhoids, radiation dermatitis and fatigue. **Objective:** To evaluate the effect of an instructional module on acute side effects of intensity modulated radiotherapy for patients with cancer prostate. Settings: The study was carried out in the radiotherapy unit at Ayadi Almostakble Charity Hospital, Egypt. Subjects: Random sample of 90 adult patients, who were divided in to two equal groups. Study group received an instructional module for acute side effects& routine hospital care, while control group received only routine hospital care. Tools: three tools were used. Tool one: "patients with cancer prostate; sociodemographic& clinical data ". Tool two: "patient's knowledge regarding cancer prostate& intensity modulated radiotherapy structured interview schedule" and tool three" cancer prostate: acute radiotherapy side effects& action taken: structured interview schedule". Results: The study showed that there was a significant improvement in side effects in the study group more than in the control group (P=0.000\*). Furthermore, majority of the study groups exhibited satisfactory level of practice to reduce these side effects (P = <0.001\*). Conclusion: The patients with prostatic cancer received educational program had significant improvement of knowledge and self-care practice than the control group. Recommendations: In service training program should be carried out for nurses working in radiotherapy department, about acute radiotherapy side effects and its management.

**<u>Keywords</u>**: Intensity modulated radiotherapy, acute side effects, and instructional module.

### Introduction

Prostate cancer (PCa) is a malignant tumor that usually caused by many epigenetic alteration that lead to uncontrolled proliferation, differentiation and invasion to nearby tissues. PCa represents 14.0% of all new cancer cases in the United States in 2022 and 5.7% of all cancer deaths. In Egypt, the incidence of PCa 7.2% and the mortality rate 10.2% in 2022 (Kulothungan et al., 2022). Over the past few decades, there have been significant advances in the delivery of

radiotherapy. These include developments in treatment planning systems and linear accelerator delivery capabilities, which reduce the risk of toxicity and morbidity as well as more advanced imaging techniques, which have improved the accuracy of target volume definition and delineation as intensity modulated radiotherapy (IMRT) (Cho, 2018, D et al., 2019). Despite being the most recent and essential in the treatment of prostate cancer, intensity modulated radiation therapy; however have certain negative side effects (Grégoire et al., 2020).

Radiotherapy effects side classified as acute (early) or chronic (late). Acute side effects are caused by damage to normal cells in the area being treated, they occur during treatment and up to six months after treatment has finished, also side effects tend to start a week or 2 after the radiotherapy begins. The most common acute radiotherapy side effects on prostate; it includes urinary as urgency, frequency and dysuria, also early rectal toxicities develop during the course of radiation therapy and typically persist for <90 days after the completion of treatment. These symptoms include loose stools or diarrhea, tenesmus, urgency, severe anorectal pain, irritation of hemorrhoids, and bleeding (Serrano, Kalman, & Anscher, 2017; Sutton et al., 2021).

Patients with prostate cancer can face problems about body structure and functions, activity, and participation which may limit their participation to life. So they require skilled and supportive care from the initial process of diagnosis through clinical reasoning and treatment to post treatment periods. An instructional module may help men regain their performance and independency and maintain the highest quality of life (Huri, Akel, & Şahin, 2016).

Oncology nurses have a great chance to improve their patient's radiotherapy side effects as they spend large portions of time with the patient. She acts as teachers, care providers, researchers, consultants, and managers. Therefore, the nurses have a major role in developing effective an instructional program or module for patients with cancer prostate to manage their acute intensity modulated radiotherapy side effects and assisting patients in performing effective self-care management (Rosen, et al., 2018).

# Aims of the Study

This study aims to evaluate the effect of an instructional module on acute side effects of intensity modulated radiotherapy for patients with cancer prostate.

# Research hypotheses

• Patients with cancer prostate undergoing intensity modulated radiotherapy who receive proposed instructional module exhibit fewer side effects than those who received routine nursing intervention.

## Materials and Method

#### **Materials**

<u>Design:</u> Randomized control trial was utilized to conduct this study.

<u>Settings:</u> This study was conducted in the Radiotherapy Unit at Ayadi Almostakble Charity Hospital, Alexandria. It contains 5 linear accelerators machine in addition to positron emission tomography (PET-CT) for simulation prior radiotherapy and brachytherapy unit.

<u>Subjects:</u> Random sample of 90 adult patients admitted to the above mentioned settings and diagnosed with prostate cancer undergoing intensity modulated radiotherapy was included in the study. The sample was divided into two equal groups (45 patients in each group), the control group, and group the study group. The sample size was calculated using power analysis (Epi-info7) program based on the following parameters: population size = 120/6months, expected frequency =50%, acceptance error =5%, confidence coefficient =95%.

<u>Tools:</u> In order to collect the necessary data for the study three tools were used:

Tool one: "Patients with cancer prostate; sociodemographic& clinical data". This tool was developed by the researcher after reviewing related literature. This tool was used to elicit baseline data of patients with cancer prostate. It consists of two parts:

Part I: Patients' socio-demographic: Such as age, gender, level of education, sex, marital status, and occupation, marital status, occupation, income and residence area.

Part II: Patient's clinical data: Such as family history of cancer, medical and surgical history, history of smoking, causes of previous hospitalization, present complaints, time of starting treatment, prescribed medication, date finishing treatment...etc.

Tool two: Patient's knowledge regarding cancer prostate& intensity modulated radiotherapy structured interview schedule: It developed by the researcher based on literature review (Tamanoi et al., 2020), and used to assess patient's knowledge about cancer prostate, acute side effects of intensity modulated radiotherapy and action taken. It consists of three parts:

Part I: Patient's knowledge related to cancer prostate: This part was involved 8 close ended questions to assess patient's knowledge related to the following areas: cancer, stages of cancer prostate, line of cancer treatment... etc.

Part II: Knowledge related to side effects of radiotherapy: This part was involved 9 close ended questions related to the effect of radiotherapy, side effects, degree or severity of side effects ...etc.

Part III: Knowledge related to action taken for side effects: This part was included open ended questions about how the patient deal with each side effects of radiotherapy

Tool three: Cancer prostate: Acute radiotherapy side effects& action taken: structured interview schedule: This tool

was developed based on literature review (Gillessen et al., 2020), to assess severity of acute radiotherapy side effects as well as patient actions toward these side effects. It consists of four parts:

Part I: QUFW94 questionnaire: This part was adapted by researcher from the original QUFW94 questionnaire was developed by (Hajdarevic et al., 2016), it was subdivided into four main categories: General section, urinary problems, intestinal problems, Sexual function.

Part II: Action taken toward acute intensity modulated radiotherapy side effects: This part was developed by the researcher based on relevant literature, to assess and describe how the patient with cancer prostate deals with acute intensity modulated radiotherapy side effects.

Part III: Urine culture& microbial resistance: This part was developed by the researcher based on relevant literature (Roviello et al., 2017), to assess type of microorganism as well as type of antibiotic sensitive to it.

**Part IV:** This part was adopted from. It assessed anorectal pain through 100 mm line on which the extreme left of the line indicates no pain and the extreme right indicated severe and unbearable pain.

## Method

Approval of the ethics committee of the faculty of nursing was obtained. An official approval to conduct this study was obtained after providing explanation of the aim of the study. An informed consent was obtained from the patients. The study tools were tested for content validity by 5 experts in the field of the study. The necessary modifications were done accordingly. A pilot study was carried out on 10% of the study sample in order to test the clarity and applicability of the research tools. Reliability of the tools was tested using Cronbach's Alpha test.

The reliability coefficient was 0.736 for tool two and 0.737 for tool three which is acceptable.

The study was conducted in three phases: Phase I: Initial assessment of all patients (study and control group) was carried out once the patient immediately scheduled for radiotherapy to collect sociodemographic and clinical data, assessment of acute radiotherapy side effects and action taken.

**Phase II:** Priorities and outcome were formulated based on the assessment phase, the content was organized according to a feasible learning sequence (from easy to difficult) to enhance patients' understanding. A colored booklet was developed in simple Arabic language to be distributed to each patient of the study group and was included the following: Simple anatomy & physiology of the prostate gland, definition & risk factors of cancer prostate, information regarding acute side effects of radiotherapy such as urinary tract infection, dysuria, severe anorectal pain, diarrhea, hemorrhoids. radiation dermatitis, fatigue and insomnia.

Phase III: Implementation phase: An instructional module will be implemented individually for each patient of the study group in the above mentioned setting in 5 sessions, each session will continue for 45-60 minutes. These sessions will be carried out within first week of radiotherapy. Patient will be asked to bring one of the family members to attend instruction for follow up of patient at home.

**Phase IV: Evaluation phase:** All patients in both groups will be evaluated pre radiotherapy application, immediately after treatment is finished and the first month (every two weeks) post application of the instructional module.

## **Ethical considerations:**

Written informed consent was obtained from patient after explaining the aim of the study and the right to refuse to participate in the study and/ or withdraw at any time.

Patient's privacy was respected. Confidentiality of the collected data will be ascertained.

## Statistical Analysis

The collected data were organized, tabulated and statically analyzed using the statistical package for social studies (SPSS) Version 25.0. Qualitative data were described using number and percent. Quantitative data were described mean  $\pm$  standard deviation. Finally analysis and interpretation of data were conducted. P-values of 0.05 or less were considered statistically significant.

## Results

**Table 1** presents the frequency distribution of patients with prostatic cancer groups of both control and study groups according to their sociodemographic data. There was no significant difference between two groups in relation to sociodemographic data.

**Table 2** shows comparison between control and study group patients with prostatic cancer regarding their total knowledge score pre and 2weeks post implementation of educational program. It was found that all control group (100%) had un satisfactory level of knowledge regarding radiation therapy pre and post educational program, However the majority (80.0%) of the study group patients showed marked improvement in their knowledge in the 2nd week post educational program application with significant difference (P=<0.001\*).

**Table 3** illustrates comparison between control and study group patients with prostatic cancer regarding severity of radiotherapy side effects pre and 8 weeks post implementation of educational program according to the levels and mean scores of QUFW94 questionnaire. It was found that all control group (100%) had moderate side effects pre and post educational program, however the study group patient showed

marked improvement in overall severity of side effects post educational program application. The difference was highly statistically significant within the study group patients (X2c=90.00, P=0.000\*).

Table 4 illustrates comparison between control and study group patients with prostatic cancer regarding action taken acute toward intensity modulated radiotherapy side effects pre and 8 weeks post educational program. It was found that all control group (100%) had un satisfactory level of practice pre and post educational However There program, was improvement 8 weeks post educational program application as the majority of study group (95.6%) had satisfactory level of difference practice. The was statistically significant within the study group patients (P = <0.001\*).

## Discussion

Cancer prostate is the second most common cancer diagnosed in men, and the fifth most common cause of cancer death for males worldwide associated There are many risk factors disease. associated with the development of PCa mainly age and heredity. Early detection of PCa in most cases is done through digital rectal examination or by measuring the serum concentration of prostate specific antigen (PSA) (Tan, ElShafei, Aminsharifi, Khalifa, & Polascik, 2020).

As regard patients overall knowledge about cancer prostate, radiotherapy and acute radiotherapy side effects pre implementation of educational program, the results of the current study showed that the studied patients had un satisfactory level of knowledge pre educational program application. This finding may be attributable to the fact that the study was conducted at a free government hospital and that the majority of the patients were retired or unemployed due to their lower economic standards. Furthermore, the current study results revealed that there was statistically significant improvement among

the study group than control group regarding total knowledge after 2weeks from implementing educational program. This improvement in patient's knowledge may be attributed to the fact that utilizing various teaching techniques, such as power point slides, videos, posters, and colored booklets; discussion and researcher reiteration of information received at the end of each session (World Health Organization, 2021).

The main findings of the current study revealed that there was statistically significant improvement among the study group than control group regarding severity of these side effects. This indicates that the study group's adherence to healthy practices improved as a result of the educational program that was provided. The introduction of educational program helped the subjects of the current study gain self assurance, the ability to access resources to meet needs, and self management skills.

This study agreed with (Garcia et al. 2021) reported that regardless of the type of treatment, cancer patients should demand information about the side effects of radiotherapy and action that can be taken to minimize them. They reported that the early implementation of the ACR phase in patients with ACS is helpful in improving cardiac function, lowering the occurrence of adverse events, and enhancing quality of life, which has clinical value for promotion and application.

In relation to overall patient's action taken toward acute intensity modulated radiotherapy side effects, the results of the current study showed that there was no statistically significant difference between study and control group pre implementing of educational program. This finding may be due to that the majority of the study subjects were unaware of the self care practices for managing acute radiation side effects since the researched patients had insufficient awareness of these practices. This is in line with (Halkett et al. 2016) reported that the

radiation oncologists should educate patients during first consultations prior to treatment. This was also successful in raising patient awareness and improved practice toward procedural problems and steps taken to minimize radiotherapy side effects.

Furthermore, the current study results statistically revealed that there was significant improvement among the study group than control group regarding total action taken after 8 weeks after implementing program. educational From researcher's point of view, this improvement was brought about by constant follow up with the patient, repeated demonstrations of the practice at regular intervals during the five days of sessions the patient received each week. These results in accordance with (Arlinghaus & Johnston 2018) stated that health education is a useful strategy for raising awareness and changing people's attitudes toward their health.

Furthermore, the previous findings reflect that, beneficial effect of supportive educational interventions on the self care practices and health outcomes and educating patients are important for preparing them both physically and psychologically to decrease anxiety, fears and misconceptions considering that radiotherapy treatment. As a result, the teaching of self care methods seems critical to improving the person's self care ability. It was found that self care training improved the QOL and life expectancy of patients with cancer who were under radiotherapy. Therefore, self care training is recommended to improve the QOL and the life expectancy of cancer patients (Kaasa et al., 2018).

Finally, the present study emphasized that a well planned self care practice guidelines carried out by the researcher could be a successful tool to help in improving prostatic cancer patients self care related to acute intensity modulated radiotherapy side effects and essential information should be included about; disease, treatment, side effects of treatment, importance of follow up

and compliance with treatment. Nurses play an important role in planning and applying teaching program. Successful implementation combines education for patients, training for nurses in the context of an organization committed to both the concept and practice of supported teaching program (Ko et al., 2016).

## Conclusion

Based upon the findings of the current study, it could be concluded that there were not statistically significant differences among study and control group implementation of educational program. There statistically significant were improvement was observed in knowledge and self care practice related to acute intensity modulated radiotherapy side effects of the study group than in control group after application of educational program.

#### Recommendations

In line with the findings of the study, the following recommendations are made:

- A teaching session concerning the prostate side effects of acute radiotherapy should be attended by newly hired nurses in the radiotherapy department.
- Update standards of care for acute radiotherapy side effects of prostatic cancer patients according to international guidelines.
- Administrators should schedule recurring patient education sessions on acute radiation side effects and how to handle them as part of hospital policy and procedure.

Table (1): Frequency distribution of patients with prostatic cancer of both control and study groups according to their sociodemographic data

Casiadamagnahia	C4		Control			
Sociodemographic	Study		Control		2	D
Data	(n = 45)	Ι	(n = 45)	T	$\chi^2$	P
	No.	%	No.	%		
Age						
20 < 30	0	0.0	0	0.0		
30 < 40	0	0.0	0	0.0	0.058	0.809
40<50	12	26.7	11	24.4	0.038	0.809
50 <or 60<="" td=""><td>33</td><td>73.3</td><td>34</td><td>75.6</td><td></td><td></td></or>	33	73.3	34	75.6		
Mean $\pm$ SD.	$52.02 \pm 5$	5.23	$52.22 \pm 5$	5.76	t=0.172	0.864
Marital status						
Married	45	100.0	43	95.6	2.045	FEp=
Divorced	0	0.0	2	4.4	2.043	0.494
Level of education						
Illiterate	29	64.4	21	46.7		<sup>MC</sup> p=
Read and write	16	35.6	23	51.1	3.443	0.141
Primary	0	0.0	1	2.2		0.141
Residence						
Urban	0	0.0	2	4.4	2.045	$^{FE}p=$
Rural	45	100.0	43	95.6	2.043	0.494
Occupation						
Manual work	1	2.2	2	4.4		
Office works	7	15.6	7	15.6	0.007	$^{MC}p=$
No work	15	33.3	17	37.8	0.805	0.910
Retired	22	48.9	19	42.2		
Income						
Enough	0	0.0	2	4.4	2.045	$^{\mathrm{FE}}p=$
Not enough	45	100.0	43	95.6	2.045	0.494

Table (2): Comparison between control and study group patients with prostatic cancer regarding their total knowledge score pre and 2weeks post implementation of educational program

Knowledge	Study (n = 4				Contro (n = 45			II (n.)	$\mathrm{U}(\mathrm{p}_2)$		
Knowledge	Pre		Post		Pre		Post		$U(\mathbf{p}_1)$	$O(\mathbf{p}_2)$	
	No.	%	No.	<b>%</b>	No.	%	No.	<b>%</b>			
Unsatisfactory <60%	45	100	9	20.0	45	100	45	100.0		$\chi^2 = 60.00^*$	
Satisfactory ≥60%	0	0.0	36	80.0	0	0.0	0	0.0		(<0.001*)	
$McN(p_0)$											
Total score											
Min Max.	8.0 - 1	6.0	22.0 - 38.0		7.0 - 1	6.0	7.0 - 1	6.0			
Mean $\pm$ SD.	11.69	$\pm 2.70$	33.84	$\pm 6.05$	10.89	± 3.45	11.20 =	± 3.31			
Median	13.0	13.0			9.0		10.0		024.50	$0.00^{*}$	
% Score									934.50 (0.523)	0.00 (<0.001*)	
Min Max.	21.05	-42.11	57.89	- 100.0	18.42 -	- 42.11	18.42 -	- 42.11	(0.323)	(<0.001)	
Mean $\pm$ SD.	30.76	± 7.09	89.06	± 15.92	28.65	± 9.07	29.47 =	± 8.72			
Median	34.21		97.37		23.68		26.32				
$\mathbf{Z}\left(\mathbf{p}_{0}\right)$		5.8	61*(<0	.001*)		0.	471 (0.0	638)			

Table (3): Comparison between control and study group patients with prostatic cancer regarding severity of radiotherapy side effects pre and 8 weeks post implementation of educational program according to the levels and mean scores of QUFW94 questionnaire

C' Jo offerste			Stud	ly group (N= 45)			Contr	Test of Significance		
Side effects	No. Pre			Post		Pre				
			No.	%	No.	% No		%		
Total QUFW										
- No/mild problem	0	0.0	45	100.0	0	0.0	0	0.0		
- Moderate problem	45	100.0	0	0.0	45	100.0	45	100.0		$X^{2a}=NA$
- Major Problem	0	0.0	0	0.0	0	0.0	0	0.0	$X^{2b}=90.00$	P=0.000*
- Test of Significance	X <sup>2c</sup> =90.00 P		=0.000*		X <sup>2d</sup> =NA					
- Mean ± SD	45.93±1.543		21.31±2.539		45.98±3.243		43.16±1.705		ta=0.007	P=0.934
- Test of Significance	t°=55.588 P=		=0.000*		t <sup>d</sup> =5.10	63 P=	*000.0		t <sup>b</sup> =47.917	P=0.000*

Table (4): Comparison between control and study group patients with prostatic cancer regarding action taken toward acute intensity modulated radiotherapy side effects pre and 8 weeks post educational program

o weeks post education	ona	ı Pı	. 05	ı																	
Side effects of radiotherapy		<b>Study</b> (n = 45)							Control(n=45)												
		Pre		Post			P		Pre		P	Post			Test of	sig (	p <sub>1</sub> T	Test of sig (			
		No.		<b>%</b>	% N		0. %		N	No.		%		No.		o O					
Satisfactory ≥60%		0		0.0	)	42		93.3	0		0.	.0	0		0	.0					
Overall																					
Unsatisfactory <60%	45	i	100		2		4.4	45	i	100		45		100							
Satisfactory ≥60%	0	0.0		)	43		95.6	0		0.0		0		0.0							
% Score																		$\chi^2$	$\chi^2 = 82.340^*$		
Min. – Max.	23	23.33–36.19		19	9 50.		50.0 - 100.0		.33–39.83		3	25.24-		-37.65						.001*)	
Mean $\pm$ SD.	30	$0.39 \pm 3.98$		95.38±12.5		3 29	.53	$53 \pm 3.48$		29.37		$37 \pm 3.12$									
Median	30	30.0		100.0		29	29.05		29.0		05										
$Z(p_0)$	5.8	845*	(<0.	.001	*)			0.	971	(0.33	1)										

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