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Profile of Radiotherapy Side Effects in Patients Treated for Cervical Cancer in Cameroon: Case of the Douala General Hospital

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Abstract

Background: Radiotherapy is one of the main therapeutic strategies used in cervical cancer. The first radiotherapy services in Cameroon have existed since 1987 and still treat by conventional radiation techniques. With the evolution of radiation techniques, acute, subacute, and late complications are minimized. Our study aimed to describe the profile of side effects in patients with uterine cervix cancer treated by conventional radiotherapy, still used in our services. **Methods:** This was a retrospective and descriptive study of the records of patients treated in the radiotherapy department of the Douala General Hospital from January 2015 to December 2019. Data concerning radiation-induced toxicities were collected using the CTCAE Version 4.0 classification. Data analysis was performed using SPSS version 20.0. **Results:** A total of 270 records were selected. The median age was 54 years. The mean total radiation dose was 55.9 ± 11.8 Gy and 71.1% of patients were treated for less than 8 weeks. We found a frequency of 66.7% of radio-induced lesions with 99% being acute. The main acute lesions encountered were radio dermatitis (40%), radiation cystitis (17.7%), and radiation proctitis (17.1%). As late lesions, we found one case of vaginal fibrosis (0.4%). Exclusive radiotherapy, classical fractionation, and total doses lower than 45 Gy seemed to decrease the toxicity linked to conventional radiotherapy. **Conclusion:** The frequency of side

effects of radiotherapy for cervical cancer at the Douala General Hospital remains high. Early lesions are the most encountered but strategies should be put in place to better evaluate late lesions.

Keywords

Cervical Cancer, Radiotherapy, Radiation-Induced Lesions, Cameroon

1. Introduction

Radiotherapy is a conservative, locoregional therapeutic strategy that uses the ionizing properties of electromagnetic or corpuscular radiation to treat mainly malignant diseases [1]. It is mainly used in oncology as a treatment modality with or without surgery and/or chemotherapy, targeting the primary tumor, satellite lymph nodes, and often certain metastases [1]. One of its main indications is cervical cancer, which is the second most frequent cancer in Africa [2] [3] [4]. In Cameroon, cervical cancer is the leading cause of cancer-related deaths with an estimated mortality rate of 65.4% [2] [3]. Radiation therapy in cervical cancer can be exclusive or concurrent with chemotherapy [1] [4]. Its aim is to deliver the maximum dose of radiation to the pelvis (the tumor and its extensions) while minimizing the doses received by the surrounding healthy organs, which may, however, be subject to toxicity [1] [4]. Several studies have reported radiation-induced toxicities including radiation cystitis with frequencies varying from 22.1% to 44%; radiation proctitis with a frequency of 31.3%; radiodermatitis, radiation enteritis at 13.3% [5]. This has led to improved radiation techniques aimed at minimizing radiation induced toxicity on normal tissue [1]. In Cameroon, radiotherapy is delivered in a single public center, covering 22 million inhabitants, and treatment is by conventional radiation techniques using gamma radiation from a Cobalt-60 source. We therefore sought to carry out this study which aimed to describe the toxicity profile of conventional radiotherapy in patients treated for cervical cancer in Cameroon. The purpose is to advocate for an upgrade in equipment and techniques in radiation oncology in Cameroon.

2. Methods

We conducted a retrospective, descriptive and analytical study over a 5 year period (from January 2015 to December 2019) in the radiation oncology department of the Douala General Hospital. We consecutively included all records of patients with histologically proven cervical cancer who had received external pelvic radiotherapy with or without chemotherapy and/or surgery. All records with incomplete information, missing or incomplete radiotherapy technical records, were excluded. Prior authorization from the Institutional Ethics Committee of the Faculty of Medicine and Biomedical Sciences of the University of Yaoundé I and the Douala General Hospital were obtained. Data collection was done using pre-established and pre-tested survey forms. The variables of interest were age,

FIGO stage, total dose, fractionation, treatment protocols, early and late side effects. Early side effects were defined as lesions that appear during and immediately after radiation therapy, and reversible within the months following treatment [1]. Late side effects occur, by definition, more than 6 months after the beginning of radiation without any tendency to regress, even if their functional impact may vary over time [1]. We used the National Cancer Institute's CTCAE (Common Terminology Criteria for Adverse Events) V4.0 for the description of adverse events in our study population as shown in **Table 1** [6].

Table 1. Toxicity scoring principle in the Common Terminology Criteria for Adverse Events (CTCAE) v4.0 scales [6].

Grades	Toxicities
Grade 1	A mild or minimal adverse event, usually asymptomatic, that does not interfere with any function and does not require treatment or intervention
Grade 2	Moderate adverse event, usually symptomatic, requiring interventions such as local treatments, they may or may not interfere with function but not interfere with activities of daily living
Grade 3	Severe adverse event requiring serious interventions or even hospitalization
Grade 4	Life-threatening or disabling adverse event; disability
Grade 5	Death related to the adverse event

The data collected was entered using CSPRO 7.3 software. SPSS version 20.0 and Microsoft Office Excel 2016 software were used to process the data. The analyses was done in two stages, first a descriptive analysis of the results, followed by a bivariate analysis using the chi-square test and Fisher's exact test to search for factors associated with the occurrence of side effects. The threshold of statistical significance was below 0.05. Our results are presented in tables and graphs.

3. Results

A total 270 records were included in our study.

3.1. Demographic and Clinical Characteristics

The median age of our population was 54 years with extremes of 26 and 90 years. The majority of patients (30.4%) were in the age range [50 - 60 years] as shown in **Figure 1**. HIV infection (5.9%) and smoking (4.8%) were the most common comorbidities among the patients. The most represented histological type in our population was squamous cell carcinoma with a proportion of 93.3%. FIGO stages II (37.03%) and III (30%) were the most identified. **Figure 2** presents the distribution of the population based on the FIGO stages.

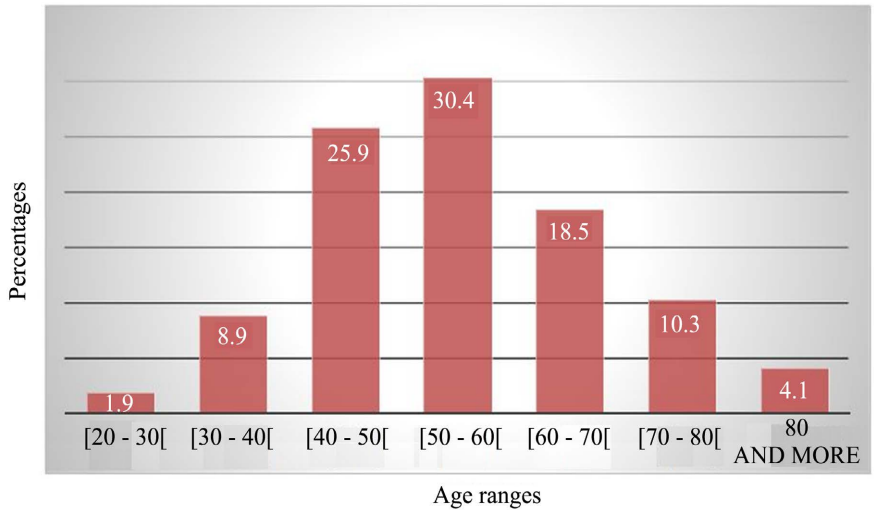

Figure 1. Age distribution of patients.

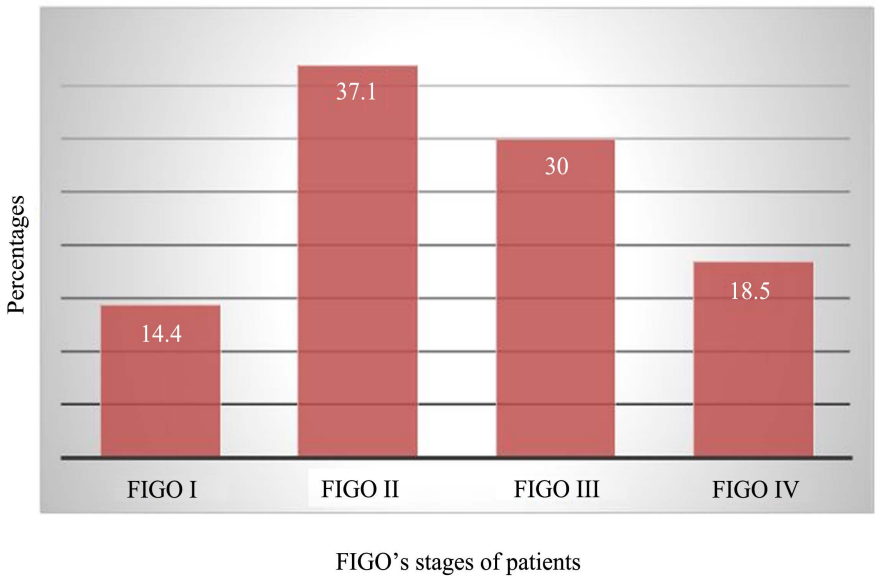

Figure 2. Distribution of the population based on the FIGO stages.

3.2. Therapeutic Data

In our study population, external radiotherapy was curative in 93.7% of cases (n = 253) and palliative in 6.3% of cases (n = 17). The most common therapeutic modalities used in our study were concurrent chemo radiation (63.3%) and exclusive radiotherapy (19%). Surgery was combined with exclusive radiotherapy for 11% of patients, or with concurrent chemo radiation in 7% of patients. The average total radiation dose delivered was 55.9 ± 11.8 Gray. Among the patients, 50.4% (n = 136) had received a dose > 60 grays and 49.6% (n = 134) a dose < 60 grays. Regarding fractionation, it was conventional in the majority of patients (n = 162 or 60%). Hypofractionation at 3 Grays per session was used in 15 patients (5.6%). Table 2 shows the distribution of patients according to total dose, type of fractionation, and schedule.

Table 2. Population distribution by total dose, fractionation, and schedule.

Variables	Number (n)	Percentage (%)
Total dose (in Gray)		
<60	134	49.6
≥60	136	50.4
Fractionation (in Gray)		
2	162	60
2.5	93	34.4
3	15	5.6
Schedule (in days)		
<55	192	71.1
55 and over	78	28.9

The mean schedule time was 44.6 ± 21.8 days; duration of treatment of less than 55 days was applicable to 71.1% of patients with a mean total dose of 55.9 ± 11.8 Grays.

3.3. Evolution

The occurrence of both early and late side effects was observed in 66.7% (n = 180) of patients. The most common side effects were cutaneous-mucosal, genitourinary and gastrointestinal, represented in order of frequency by radiodermatitis (40%, n = 108/180), radiation cystitis (17.7%, n = 48/180) and radiation proctitis (17.1%, n = 46/180). Grade II toxicities were predominant. Vaginal fibrosis was the identified late toxicity in our patients. **Table 3** shows the distribution of patients by type of side effect and grade.

Table 3. Distribution of patients by side effects and grade.

Side effects	Number (%)	Grade I (%)	Grade II (%)	Grade III (%)
Acute lesions				
Mucocutaneous lesions				
Radiodermatitis	108 (40)	12 (4.4)	89 (32.9)	7 (2.5)
Loss of pubic hair	29 (10.7)	10 (3.7)	19 (7)	-
Mucosal dryness	11 (4.1)	11 (4)	-	-
Gastrointestinal lesions				
Radicular proctitis	46 (17.1)	5 (1.8)	40 (14.8)	-
Radiation enteritis	31 (11.5)	-	31 (11.4)	-
Hemorrhoids	3 (1.1)	-	3 (1.1)	-

Continued

	Genitourinary lesions			
Radiation cystitis	48 (17.7)	20 (7.4)	24 (8.8)	2 (0.7)
	Others			
Lymphedema	2 (0.7)	-	2 (0.7)	-
	Late lesions			
Vaginal fibrosis	1 (0.4)	-	1 (0.4)	-

3.4. Factors Associated with the Occurrence of Side Effects

- Bivariate Analysis: Therapeutic Data and Occurrence of Side Effects

On bivariate analysis, the occurrence of side effects was lower in patients treated with exclusive radiotherapy with a statistically significant difference (p = 0.03) as shown in Table 4; patients who received a total dose higher than 45 grays had more side effects with a p value < 0.001) as shown in Table 5. Conventional fractionation was significantly associated with the occurrence of acute side effects) as shown in Table 6.

Table 4. Distribution of patients according to treatment protocols and occurrence of side effects.

Variables	Side effects		OR (95% CI)	p-value
	Yes	No		
Exclusive RT	27 (15.0)	23 (25.6)	0.51 (0.28 - 0.96)	0.03
RT*+CT	115 (63.9)	56 (62.2)	1.07 (0.64 - 1.83)	0.78
RT+CH**	21 (11.7)	8 (8.9)	1.35 (0.58 - 3.19)	0.48
RT+CT***+CH	17 (9.4)	3 (3.3)	3.03 (0.86 - 10.61)	0.08

*RT = Exclusive Radiation therapy **CH = Surgery ***CT = Chemotherapy.

Table 5. Distribution of patients by total dose received and occurrence of side effects.

Variables	Side effects		OR (95% CI)	p-value
	Yes	No		
Total dose (in Gray)				
Less than 45	22 (12.2)	29 (32.2)		
45 and over	158 (87.8)	61 (67.8)	0.29 (0.16 - 0.55)	<0.001

Table 6. Relationship between fractionation and side effects.

Variables	Side effects		OR (95% CI)	p-value
	Yes	No		
Splitting (in Gray)				
2	105 (65.0)	45 (50.0)	1.86 (1.11 - 3.11)	
2.5	60 (35.0)	45 (50.0)	0.54 (0.32 - 0.90)	0.01

- Multivariate analysis: clinical characteristics, therapeutic data and occurrence of side effects

On multivariate analysis, a total dose of less than 45 grays, conventional fractionation and smoking were the three factors significantly ($p < 0.05$) associated with the occurrence of side effects as shown in Table 7.

Table 7. Multivariate analysis factors associated with the occurrence of side effects.

Variables	Side effects		OR (95% CI)	p-value
	Yes	No		
Therapeutic protocol RT	27 (15.0)	23 (25.6)	0.60 (0.31 - 1.15)	0.121
Total dose (in Gray)				
Less than 45	22 (12.2)	29 (32.2)	0.30 (0.16 - 0.57)	<0.001
Splitting (in Gray)				
2	105 (65.0)	45 (50.0)	1.79 (1.05 - 3.05)	0.034
Comorbidities				
Smoking	11 (6.1)	2 (2.2)	2.76 (1.21 - 3.22)	0.04

4. Discussion

This study aimed at describing the profile of side effects found in cervical cancer patients following pelvic external beam radiotherapy in Cameroon and to highlight the factors that may influence their occurrence. The median age was 54 years. Squamous cell carcinoma was the most common histological type found in 93.3% of cases (n = 252). The FIGO stages most represented in our study were stages II and III. Concurrent chemo radiation was the most frequent treatment regimen (63.3%). The mean total radiation dose was 55.9 ± 11.8 Gy and 71.1% of patients were irradiated for less than 8 weeks. We found a frequency of 66.7% of radio-induced lesions with 99% occurring early. The main acute lesions encountered were radio dermatitis (40%), radiation cystitis (17.7%), and radiation proctitis (17.1%). As late lesions, we found one case of vaginal fibrosis (0.4%). Exclusive radiotherapy, classical fractionation, and total doses lower than 45 Gy seemed to decrease the toxicity of radiotherapy.

The 50 - 60 years age group was mostly represented with a median age of 54 years, similar to findings from the Yaounde Cancer Registry and to those of Ngwayu *et al.* in 2019 in Bamenda, where the most represented age group was 50 - 54 years [7].

In our series the general characteristics of cervical cancer as histological types and stages were identical to other low and medium income countries as shown by Kantelhardt *et al.* in Ethiopia [8] who found a predominance of stage II to IV and those of Dem *et al.* in Senegal [9]. Concurrent chemo radiation was the most frequent treatment regimen in line with the late stages observed. Green's meta-analysis confirmed the benefit of concurrent chemo radiation on local control,

recurrence-free survival and overall survival [1]. It also demonstrated that exclusive radiotherapy is reserved for early forms without poor prognostic factors [1]. Hypofractionation was used for about 40% of patients. The average spread was 44 days with 71% of our population treated in less than 55 days. It is worth noting here that we used hypofractionation (2.5 to 3 Gys per fraction) in 40% of our population to improve patient turnover in the department, which is the only functional public center for the whole country with 22 million inhabitants. Radiotherapy has an action on cancerous tissues, but also on surrounding healthy tissues at the origin of side effects attributed to radiotherapy. The high percentage of acute side effects in our series are similar to those of Ozsaran *et al.* in 2003 in a retrospective and descriptive study which found acute side effects in 66.7% of patients [10] and Roszak *et al.* in Poland in 2012 who found acute side effects in 51.3% of patients [5]. In the other side, the low proportion of late lesion in our study is probably due to the lack of sufficient hindsight, to the retrospective nature of our study, to a lack of long-term follow-up linked to patients residing in other towns, and lack of health insurance which reduces compliance to proper care after initial treatment is completed.

At the difference of the acute side effects listed in our series, Ezra Niana *et al.* in Madagascar found neutropenia to be the predominant early toxicity (30.55%); it was grade 3 or 4 in 35% of cases for the combined group, against 13% for the radiotherapy group alone [11]. It was followed by digestive toxicity (23.61%) and radiodermatitis was estimated at 19.44%. These proportions are lower than those in our study probably due to our larger number of patients and the longer follow-up time. The neutropenia factor was not taken into account in our work. However, it should be noted that the high rate of radiodermatitis is consistent with the use of cobalt, given that the maximum dose is deposited at 0.5 cm under the skin. In the series by Dossou *et al.* in Rabat, the acute toxicities listed were digestive such as diarrhea (2.5%), nausea and vomiting (68%), then urinary toxicities such as acute cystitis (43%) and finally cutaneous toxicities such as radiodermatitis (11%) [12]. This distribution is different from ours. The low rate of radiodermatitis is certainly related to the use of conventional radiotherapy with X-rays having a deep yield that spares the skin for all patients. The higher urinary toxicity than that in our series could be related to the association of brachytherapy in some patients. In addition, in Iran Porouhan *et al.* in 2019 found a 20% frequency of acute gastrointestinal side effects (with symptoms such as cramps, nausea, tenesmus, diarrhea, and minor bleeding) after pelvic irradiation [13]. This difference could be explained by the use of new external beam techniques (Intensity Modulated Radiation Therapy and 3D Radiation Therapy), which improve targeting and better protect at-risk organs. The review of the literature by Viswanathan *et al.* in the USA on the side effects of pelvic radiotherapy reported 17% - 40% of acute gastrointestinal complications, 28% - 45% of early genitourinary complications, 10% - 50% of acute skin complications [14]. Late toxicity is relatively low with the use of new technologies with no skin side

effects, 16% urinary effects especially in patients treated with brachytherapy, but also gastrointestinal, bone, sexual complications [14]. It appears that in our series, toxicity remains within recommended acceptable limits, except for late lesions, which have not been sufficiently explored for the reasons mentioned above. Based on these observations, we believed it was important to identify the factors that could influence the occurrence or non-occurrence of these complications. A major factor among these was combination therapy with surgery and/or chemotherapy, which increased the risk two fold of developing side effects compared to the use of exclusive radiotherapy ($p = 0.03$). Randriamanovontsoa *et al.* in 2014 in Madagascar in a retrospective and descriptive study found early grade 3 or 4 side effects in 35% of patients for the combined group, against 13% for the radiotherapy alone group [11]. The cumulative effects of the different treatment techniques could explain this distribution. A total dose of radiation greater than 45 grays increased the occurrence of side effects in our study; the predominant occurrence of early lesions in our series depends on the cumulative dose, leading to lesions on rapidly renewing tissues. Hypofractionation seems to reduce the risk of occurrence of acute side effects in our series. Hypofractionationis, however, better known to have an impact on late complications, hence the need to better evaluate late toxicities in these patients.

5. Limitations of the Present Study

Our work did not elude the hazards and difficulties of retrospective studies (incomplete or lost medical records and radiotherapy charts, patients lost to follow-up). Chronic side effects such as fistulas, chronic radiodermatitis, secondary cancers, cystitis and chronic radial proctitis were not found, on the one hand because the follow-up of patients after 3 months was carried out with the referring physicians and on the other hand because of the delay in the appearance of certain chronic side effects which can be higher than 5 years.

6. Conclusion

At the end of our study, which aimed to describe the profile of side effects of radiotherapy in patients treated for cervical cancer in Cameroon, we found that radiotherapy induces early and late side effects in slightly more than half of the patients followed for cervical cancer, with a preponderance of acute lesions such as radiodermatitis, proctitis and radiation cystitis. Combined treatments, total dose, and hypofractionation are all factors influencing the occurrence of these toxicities. Upgrading from radiotherapy with Cobalt to linear accelerators and improving radiation techniques could dramatically improve the toxicity profile of these patients.

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Conflicts of Interest

The authors have no conflicts of interest to declare.

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Appendix: Survey Form

Topic: Profile of side effects of radiotherapy in patients treated for cervical cancer in Cameroon

Section 1: Identification

Q1: File no.	|___|___|
Q2: File number	|___|___|
Q3: Date of entry	|___|___|
Q4: Age	|___|___|

Section 2: Diagnosis

Q5: Past history/Comorbidity_____

Q6: Histological type: _____

Q7: FIGO classification
FIGO 1 = IA1 2 = IA2 3 = IB1 4 = IB2 5 = IIA 6 = IIB 7 = IIIA 8 = IIIB 9 = IVA 10 = IVB |___|

Section 3: Treatment

Q8: What is the aim of the treatment? 1 = curative 2 = palliative

Q9: Therapeutic protocols
1 = External radiation therapy
2 = Radiotherapy + chemotherapy
3 = Radiation therapy + surgery
4 = Radiation therapy + chemotherapy + surgery |___|

Q10: Other: _____

Section 4: Radiotherapy

Radiation parameters

Q11: What is the radiation protocol?

Q11A: Total dose (in gray) received	|___|__|
Q11B: Boost (in Gray)	|___|___|
Q11C: Dose per Fraction/fractionation (in Gray): 1 = 1.8 2 = 2 3 = 2.5 4 = 3	|___|
Q11D: Duration (in days)	|___|___|
Q12: Discontinue treatment before the scheduled time? 1 = Yes 2 = no	|___|

Q12A: Reason_____

Section 5: Side effects

Q13: Acute effects: (before 6 months) 1 = yes 2 = no |___|	Grade
Q14: If so, which ones?	
Q14A: Acute radiation cystitis 1 = yes 2 = no |___|	
Q14B: Acute Radiodermatitis 1 = yes 2 = no |___|	
Q14C: Mucosal dryness 1 = yes 2 = no |___|	
Q14D: Acute rectitis/proctitis 1 = yes 2 = no |___|	
Q14E: Loss of pubic hair 1 = yes 2 = no |___|	
Q 14F: Hemorrhoid 1 = yes 2 = no |___|	
Q14G: Enteritis 1 = yes 2 = no |___|	
Q14H: Others_____	
Q15: Late effects (after 6 months) 1 = yes 2 = no |___|	
Q16: If so, which ones?	
Q16A: Pelvic fibrosis 1 = yes 2 = no |___|	
Q16B: vaginal stenosis 1 = yes 2 = no |___|	
Q16C: dryness of the mucosa 1 = yes 2 = no |___|	
Q16D: Synechiae 1 = yes 2 = no |___|	
Q16E: Pruritus 1 = yes 2 = no |___|	
Q16F: Fistulas 1 = yes 2 = no |___|	
Q16F1: If yes 1 = rectoovaginal 2 = vesicovaginal |___| 3 = recto-vesico vaginal	
Q16G: Chronic Radiation Rectitis 1 = yes 2 = no |___|	
Q16H: Chronic radiodermatitis 1 = yes 2 = no |___|	
Q16I: Chronic Radiation Cystitis 1 = yes 2 = no |___|	
Q16J: Affection of the phaneras 1 = yes 2 = no |___|	