ORIGINAL ARTICLE

PREVALENCE OF ACUTE TOXICITY IN GYNECOLOGICAL BRACHYTHERAPY AT A REFERENCE CENTER IN ONCOLOGY

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Highlights: (1) Population characteristics: completed primary education and income below three minimum wages. (2) The most common neoplasm was cervical cancer. (3) The most frequent stages were IIIC1 and IIB. (4) Grade 0 radiodermatitis in 74% of the population, characterized as skin without lesions. (5) The most prevalent toxicities were dysuria and diarrhea.

PRE-PROOF

(as accepted)

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ABSTRACT

The objective of this study is to analyse the prevalence of acute toxicity in gynecological cancer patients undergoing brachytherapy at a cancer treatment center in Santa Catarina. This was a descriptive, exploratory cross-sectional study with a quantitative approach. Data were collected from electronic medical records from the oncology referral service. The population comprised patients diagnosed with gynecological cancer who started and completed teletherapy followed by brachytherapy from January to December 2022. The total population consisted of 90 women, and the main toxicity reported was grade 0 radiodermatitis, followed by dysuria and diarrhoea. Other toxicities were observed in the gastrointestinal and genitourinary systems, such as nausea, insomnia, decreased appetite, grade I radiodermatitis, fatigue, vaginal discharge, loose stools, and lower abdominal pain. Identifying the toxicity profile of women undergoing radiotherapy assists the multidisciplinary team in patient care and management.

Keywords: brachytherapy; genital neoplasms, female; uterine cervical neoplasms; radiation effects; toxicity.

INTRODUCTION

Data from 2020 indicate that gynecological cancers account for 15.25% of the estimated 8.2 million new cases of cancer in women in general, with cervical, endometrial, ovarian, and vulvar cancers being the most prominent in this category[1-2]. Cervical cancer is currently the fourth most common type of cancer in women globally, with an estimated incidence of 604,127 cases and 341,831 deaths in 2020. The mortality rate is three times higher in Latin America and the Caribbean compared to North America[3].

Human papillomavirus (HPV) is associated with 99.7% of cervical cancer cases. In this regard, prophylactic vaccines against HPV are effective in preventing infections, as well as pre-

invasive and invasive diseases of the cervix, vulva, vagina, and anus, when related to the viral types covered in the formulation[4]. In Brazil, the vaccine is distributed free of charge by the Unified Health System, with coverage between 2013 and 2021 at 75.8% among girls aged 9 to 14 for the first dose and 57.4% for the second dose, highlighting challenges regarding vaccine adherence[5]. A national concurrent cohort study conducted in the municipalities of Ouro Preto and Mariana, in Minas Gerais, demonstrated that the quadrivalent HPV vaccine was effective in reducing the prevalence of the vaccine's viral types and in decreasing the incidence of HPV infection by any type[6].

The Pap smear is the primary method used for screening cervical cancer[7], while diagnosis is usually performed by colposcopy-guided biopsy, in which samples are collected for histological examination[8]. The treatment of gynecological cancers is planned based on the clinical staging of the disease, with surgery being chosen in early stages and chemotherapy and radiotherapy being used in advanced cases[9]. For cervical cancer, the treatment of early-stage disease consists of surgery. In contrast, in advanced disease, radiotherapy is used in combination with chemotherapy, and these therapeutic approaches can cause acute toxicities[10].

Toxicities occur not only in the target organ but also in adjacent organs that are in the radiation field, and it is common for patients to experience gastrointestinal and genitourinary dysfunction. The most common gastrointestinal symptoms include pain, diarrhoea, incontinence, and bleeding, while genitourinary effects include radiation cystitis or radiation-induced urethritis, vesicovaginal fistula, and haematuria[11-12]. Considering the adverse effects inherent to radiotherapy treatment, the objective of this study was to analyze the prevalence of acute toxicity in patients with gynecological cancer undergoing brachytherapy at a cancer treatment center in Santa Catarina.

METHOD

Type of study

This was a quantitative, descriptive, exploratory, cross-sectional study.

Study location

Data were collected on-sitefrom April to June 2023 at a Specialized Oncology Care Service affiliated with the Unified Health System (SUS), which offers therapies related to the treatment of gynecological neoplasms, including teletherapy and high-dose brachytherapy. The service is located in the municipality of Florianópolis, state of Santa Catarina, Brazil. It is a referral center for cancer treatment in the state, affiliated with the World Health Organization (WHO) for palliative medicine in Brazil. However, it is not the only specialised center in the state.

Population and eligibility criteria

The inclusion criteria were: patients diagnosed with cervical cancer who started and completed teletherapy followed by brachytherapy from January to December 2022. The exclusion criteria were: individuals under 18 years of age and/or legally incapacitated, and patients who underwent teletherapy only. Thus, the study population constituted a census sample, i.e., all women who met the inclusion criteria were included. There were no missing data.

Data collection

Data were collected from electronic medical records of the oncology referral service, the Tasy® System (Philips), as well as the radiotherapy planning system, Eclipse (Varian). Data collection included sociodemographic variables such as self-declared race, marital status, education, and income, lifestyle variables such as alcohol consumption and smoking status, as well as information about the diagnosis and staging of the neoplasm, oncological therapy, and self-reported complaints of patients at the last nursing consultation after completion of high-dose brachytherapy. The data were entered into a Microsoft Excel® spreadsheet for systematisation and organisation.

Data analysis

Frequency analyses (absolute and relative) were performed to characterize the population in relation to sociodemographic data, health habits, as well as clinical information

(type of gynecological neoplasm, disease staging, chemotherapy treatment, types of surgery, and radiotherapy techniques), and, finally, information on acute toxicity in gynecological brachytherapy. The associations between the most frequent acute toxicities (dysuria, diarrhea, nausea, insomnia, and decreased appetite) and independent variables (concomitant chemotherapy and radiotherapy technique) were evaluated using contingency tables. Due to the low frequencies, Fisher's exact test was used, considering a significance level of 5%.

Ethical Aspects

The research complied with the guidelines set forth in Resolutions No. 466 of 2012 and No. 510 of 2016 of the National Health Council. The project was approved by the Human Research Ethics Committee (CEP) under opinion No. 6,225,672.

RESULTS

The population consisted of 90 women. Table 1 shows the sociodemographic characteristics of the study population, with a mean age of 48.62 years and a predominance of women aged 36–65 years (n = 69). Marital status was predominantly single (34.44%), followed by married (30%), and the most prevalent self-declared race was white (79.78%).

Table 1 - Sociodemographic characteristics of patients with gynecological cancer treated in 2022, Florianópolis-SC.

Variable	Statistic
Age (n=90)	
Mean (SD)	48.62 (12.5)
Self-reported Race (n=89)	n (%)
White	71 (79.7%)
Non-White	18 (20.2%)
Marital Status (n=90)	
Single	31 (34.4%)
Married	27 (30%)
Common-law marriage	13 (14.4%)
Divorced	10 (11.1%)
Widowed	7 (7.7%)
Not reported	2 (2.2%)
Educational Level (n=78)	
Illiterate	4 (5.1%)
Primary education	11 (14.1%)
Elementary education	26 (33.3%)
High school education	24 (30.7%)
Higher education	13 (16.6%)
Household Income (n=67)	
None	4 (5.9%)
01 to 3 minimum wages	57 (85%)
3 to 5 minimum wages	5 (7.4%)
More than 5 minimum wages	1 (1.4%)
Residence Location (n=88)	
Within Greater Florianópolis	80 (91%)
Outside Florianópolis	8 (10%)
Alcohol Consumption (n=89)	
No	77 (86.5%)
Former drinker	7 (7.8%)
Not reported	3 (3.3%)
Yes	2 (2.2%)
Smoking Status (n=89)	

No	58 (65.1%)
Former smoker	16 (17.9%)
Yes	12 (13.4%)
Not reported	3 (3.3%)

Source: prepared by the authors.

Regarding education, 33.3% of individuals have completed elementary education, and 30.77% have completed secondary education. Regarding family income, 85% earned 1 to 3 minimum wages, and most of the study population (91%) resided in Greater Florianópolis. Regarding lifestyle habits, 86.5% of patients were non-drinkers, and 65.1% were non-smokers.

Table 2 shows that the most common type of cancer was malignant neoplasia of the cervix, observed in 87.6% of patients, followed by malignant neoplasm of the endometrium with 10.1% and malignant neoplasia of the endocervix with 2.2%.

Table 2 - Clinical characteristics of patients with gynecological cancer in 2022, Florianopolis, SC.

Variable	Statistic
ICD (n=89)	n (%)
C53 – Malignant neoplasm of cervix uteri	78 (87.6%)
C54.1 – Malignant neoplasm of endometrium	9 (10.1%)
C53.0 – Malignant neoplasm of endocervix	2 (2.2%)
Previous Chemotherapy (n=88)	
No	87 (98.8%)
Yes	1 (1.1%)
Concomitant Chemotherapy (n=87)	
Yes	53 (60.91%)
No	16 (18.3%)
Not reported	10 (11.4%)
Previous Surgery (n=88)	
No	78 (88.6%)
Yes	10 (11.3%)
Type of Surgery (n=9)	
Total hysterectomy	8 (88.8%)
Partial hysterectomy	1 (11.1%)
Previous Radiotherapy (n=88)	
No	84 (95.4%)
Not reported	3 (3.4%)
Yes	1 (1.1%)
Treatment Technique(n=90)	
3D-CRT*	70 (77.7%)
IMRT**	20 (22.2%)

* 3D-CRT: Three-dimensional conformal radiation therapy.

** IMRT: Intensity-modulated radiation therapy.

Source: prepared by the authors.

Regarding associated therapeutic approaches, prior chemotherapy (CT) was performed in only one patient, representing 1.1% of the population, 18.3% did not undergo CT, and 11.4% of cases had no information on the subject. Concomitant CT was administered to 60.9% (n=53)

of the individuals, among whom 65.5% (n=X) underwent treatment with cisplatin and 4.6% (n=4) with carboplatin, while the remaining 29.8% (n=26) did not provide information on the chemotherapeutic agent. Overall, 11.3% of the patients underwent previous surgery, with eight undergoing total hysterectomy. The most frequent teletherapy treatment technique was three-dimensional conformal radiotherapy (3D-CRT), representing 77.7% of individuals, followed by intensity-modulated radiotherapy (IMRT) in 22.2% of cases.

Figure 1 shows the distribution of staging according to the guidelines of the International Federation of Gynecology and Obstetrics (FIGO). In the population, the most prevalent disease staging was IIIC1 with 25.6%, followed by IIB with 16.7%, and IIIB and IIIC2 with 11.1% each.

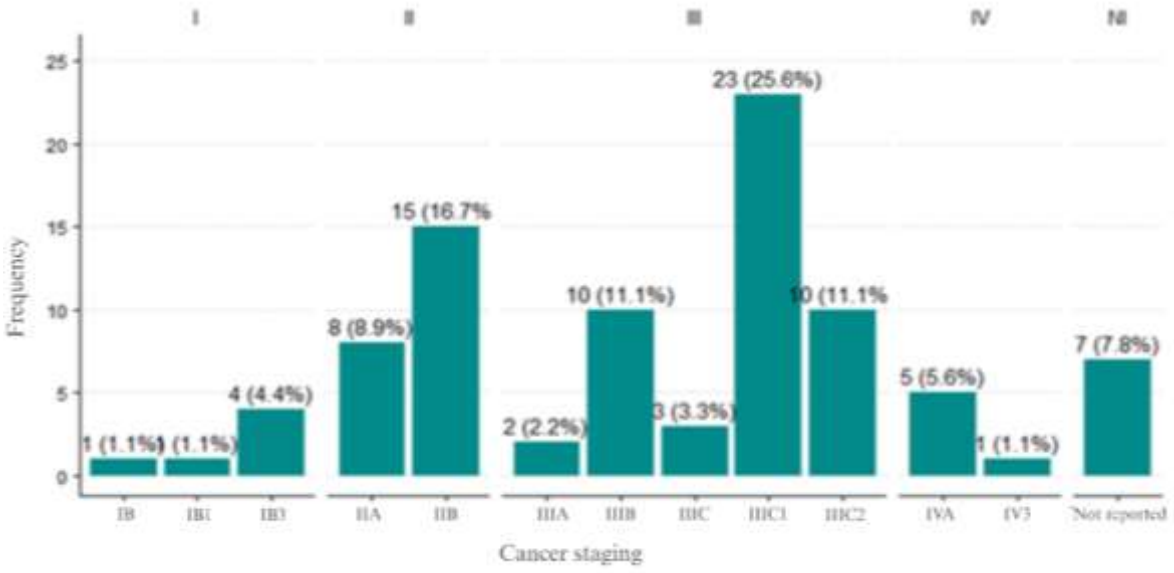

Figure 1 - Staging of the population with gynecological cancer in 2022, Florianópolis-SC. Source: prepared by the authors.

Table 3 shows the toxicities self-reported by patients during the nursing consultation in the last week of brachytherapy. Based on the findings, it can be seen that the most prevalent adverse effect of the gastrointestinal system was diarrhea, which was present in 14.4% of the population investigated, nausea in 10%, decreased appetite in 8.8%, loose stools in 4.44% and lower abdominal pain in 3.3% of the population investigated.

Table 3 - Toxicity reported by patients with gynecological cancer after brachytherapy in 2022, Florianópolis-SC.

Variable	Statistic n (%)
Grade 0 Radiodermatitis	67 (74.4%)
Dysuria	19 (21.1%)
Diarrhea	13 (14.4%)
Nausea	9 (10%)
Insomnia	8 (8.8%)
Decreased appetite	8 (8.8%)
Grade I Radiodermatitis	6 (6.6%)
Fatigue	5 (5.5%)
Vaginal discharge*	4 (4.4%)
Loose stools	4 (4.4%)
Lower abdominal pain	3 (3.3%)
Other effects**	18 (19.9%)

* Large amount, greenish and odourless.

** Pyometra, sexual inactivity, discharge (small amount, yellow and odourless), discharge (moderate/large amount, yellow and odorous), discharge (greenish with odour), confusion (level of consciousness), vaginal bleeding (originating in the intestinal loop), light vaginal bleeding, asthenia in the genital region, fever, pain in the lumbar region, grade II radiodermatitis, level of consciousness: confusion and pruritus.

Source: prepared by the authors.

Regarding the urinary system, 21.1% of patients reported dysuria during treatment. No other adverse effects on the urinary system were identified. With regard to gynecological changes, 4.4% of the population investigated reported discharge, 2.2% reported sexual inactivity, and 1.1% reported vaginal bleeding.

Table 4 shows the distribution of the five main toxicities observed according to concomitant chemotherapy and the teletherapy technique used. No associations were observed between the occurrence of [dysuria, diarrhea, nausea, insomnia, and decreased appetite] and the use of concomitant chemotherapy or with the teletherapy technique employed (3D-CRT and IMRT), since all p values were greater than 0.05. However, some symptoms were more frequent in the group undergoing chemotherapy and treated with the 3D technique.

Table 4 - Association between frequent acute toxicities and therapeutic variables in 2022, Florianópolis-SC.

	Chemotherapy n (%)				Radiotherapy Technique n (%)		
	Yes	No	Absent	p-value	3D-CRT	IMRT	p-
Dysuria	13 (68.4%)	3 (15.8%)	3 (15.8%)	1	16 (84.2%)	3 (15.7%)	0.548
Diarrhea	9 (69.2%)	3 (23.1%)	1 (7.7%)	0.7374	11 (84.6%)	2 (15.3%)	0.7248
Nausea	9 (100%)	0	0	0.1271	8 (88.8%)	1 (11.1%)	0.6775
Insomnia	6 (75%)	1 (12.5%)	1 (12.5%)	1	7 (87.5%)	1 (12.5%)	0.4769
Decreased Appetite	7 (75%)	0	1 (25%)	0.636	6 (75%)	2 (25%)	1

Source: prepared by the authors

In addition to gastrointestinal and genitourinary toxicities, the population experience other adverse effects, among which radiation-induced dermatitis, known as radiodermatitis, stands out. Radiodermatitis is classified from Grade 0 (least severe) to Grade 4 (most severe).

Grade 0 radiodermatitis was reported by 74.4% of patients, Grade I by 6.6%, and Grade II by 1.1%. Other effects included insomnia (8.8%), fatigue (5.5%), fever (1.1%), lower back pain (1.1%), and confusion (2.2%).

DISCUSSION

In the population studied, cervical cancer had a higher prevalence than other types of gynecological cancer, representing 87.6% of the sample, while endometrial cancer accounted for 10.1% and endocervical cancer for 2.2%. Considering this predominance, the discussion of clinical and sociodemographic findings is mainly similar to the characteristics described for women with cervical cancer. However, it should be noted that the data presented include women with various gynecological neoplasms, which may introduce some heterogeneity into the population profile.

The higher incidence of cervical cancer corroborates national data, in which cervical cancer is the third most common type of cancer among women, excluding non-melanoma skin cancer[13]. A study conducted by Paulino *et al.*[14] with patients diagnosed with gynecological cancer in Brazil resulted in a mean age in the sample of 48.7 years (SD 15.2). The results are similar to those found in this study, in which the average age was 48.62 years (SD 12.5), but in this study, 15 cases of cervical cancer in a young population aged 26 to 35 years stand out.

When analyzing educational level, 33.3% of patients had only completed elementary school, corroborating the study by Santos *et al.*[15] which revealed that the largest number of women with cervical cancer had completed 1 to 7 years of schooling. In addition, the literature also shows a strong association between low educational attainment and access to cervical cancer screening. Women with low educational attainment tend to have less access to knowledge about exams, preventive measures, and disease treatment, which contributes to late diagnosis and, consequently, to a high number of metastases, recurrences, and deaths.

The predominant family income in the surveyed population was between one and three times the minimum wage. Lima *et al.*[16] state that the lack of demand and difficulty in accessing preventive exams are related to low educational attainment and low socioeconomic status. Therefore, it is clear that within the population studied, there is a more vulnerable group due to

social and economic factors that can hinder access to quality health care and education, increasing inequality and distancing them from the guiding principles of the SUS, such as equity and comprehensiveness.

Regarding the population's individual characteristics, 79.7% of the women self-identified as white. A survey conducted by Rozario, Silva, Koifman and Ilva[17] of 1,004 women diagnosed with cervical cancer in the state of Rio de Janeiro found a predominance of individuals who self-identified as non-white (67.4%). This difference in results can be attributed to the prevalence of people who self-identify as white in southern Brazil[18] .

The therapeutic approach to treating cervical cancer is guided by the type of disease, staging, and individual patient factors, with surgery being indicated in the early stages. In advanced stages, radiotherapy or chemotherapy is indicated, or a combination of both. According to the data in Figure 1, the most common stages in the surveyed population are IIA-IIIC2, with a higher prevalence of IIIC1. These represent more advanced stages, which may imply a more aggressive therapeutic approach, potentially increasing the risk of adverse effects. In addition, the data may reflect an inefficiency in early diagnosis, which is important for a positive prognosis.

The most common treatment was a combination of radiotherapy and chemotherapy, and 88.6% of the population did not undergo prior surgery. This therapeutic approach is in line with evidence recommending the combination of chemotherapy and radiotherapy for cervical cancer in more advanced stages[1].

Treatment involving chemoradiation is associated with increased treatment-related toxicities, but this association was not observed in this study. According to Boer *et al.*[19] adjuvant chemotherapy administered during and after pelvic radiotherapy had greater serious adverse effects compared to the toxicity reported by patients who underwent radiotherapy alone. Regarding radiotherapy techniques, both 3D-CRT and IMRT are recommended for treatment, and both are used at the radiotherapy service surveyed, with 3D-CRT predominating. However, studies indicate that the use of IMRT is associated with lower gastrointestinal and genitourinary toxicities compared to 3D-CRT[20-21].

Based on the findings, the population exhibited toxicities in the gastrointestinal and genitourinary systems, as well as radiodermatitis. The toxicity of radiotherapy results from

irradiation of healthy tissues adjacent to the treatment area. With a view to preserving organs surrounding the target volume, ICRU 38 (International Commission on Radiation Units and Measurements)[22] establishes maximum dose limits for organs at risk in intracavitary brachytherapy. According to the guideline, it is acceptable for up to 80% of the prescribed dose to reach the rectum, 85% to reach the bladder, and 60% to reach the sigmoid colon. Despite planning with dose restrictions in organs at risk, several acute adverse effects are observed, as these are inherent to radiotherapy treatment.

Among the most common symptoms of radiation therapy are fatigue, nausea and vomiting, mucositis (inflammation of the mucous membranes), loss of appetite, dysuria (difficulty or pain when urinating), vaginal irritation, increased urinary frequency, difficulty emptying the bladder, intestinal cramps, diarrhea, fecal leakage, vaginal discharge and bleeding, menopause-like symptoms such as hot flashes, edema in the limbs and pain, tingling or numbness in the extremities, insomnia, and dyspnea (difficulty breathing)[23]. When comparing the findings of this research with the aforementioned study, the reported adverse effects are consistent, including diarrhea, nausea, loss of appetite, dysuria, discharge and bleeding, insomnia, and fatigue.

Regarding toxicities, there was a high frequency of dysuria in the population; however, no other adverse effects on the urinary tract were observed. In this regard, urinary dysfunction may also occur late, after treatment ends[24]. Regarding gastrointestinal symptoms, diarrhea was the most common among the population surveyed. The standard treatment technique for the pelvis uses anterior, posterior, and lateral radiation fields to form a rectangular distribution. The onset of this toxicity may be related to the target treatment volume, which covers part of the rectum and sigmoid colon[25]. Management and care include guidance on adopting a high-fiber diet, combined with adequate hydration, as essential measures for symptom control. In cases of diarrhea, antidiarrheal drugs may be indicated, depending on each patient's clinical needs[26].

As for adverse effects on the genital system, there were cases of vaginal discharge, vaginal bleeding, and sexual inactivity. Therapeutic approaches such as chemotherapy and specifically radiotherapy can cause symptoms such as sexual, urinary, and intestinal dysfunction, which affect women with gynecological cancer undergoing oncological treatment, leading to a decline in their quality of life due to emotional and physical dysfunction, making

them more susceptible to mood disorders[27]. These symptoms have significant psychosocial impacts, highlighting the need for comprehensive care in the therapeutic process of cancer patients.

Grade 0 radiodermatitis was a frequent symptom in the population. According to the Radiation Therapy Oncology Group (RTOG), this classification describes skin without alteration, with tissue damage beginning at grade 1 and progressing to mild tissue atrophy, changes in skin pigmentation, and hair loss[28]. According to Fan *et al*.[29] acute radiodermatitis is defined as changes in the skin occurring within 90 days after treatment, while chronic radiodermatitis is defined as changes occurring after this period. Patients undergoing teletherapy followed by brachytherapy are likely to develop some degree of radiodermatitis after discharge. For this reason, it is necessary to monitor these patients to assess their skin condition and provide guidance and appropriate care[24].

The nursing team in radiotherapy works in the prevention, health promotion, and rehabilitation of patients undergoing therapy for gynecological cancers. These professionals play a central role in explaining treatment, potential adverse effects, and necessary care, using skilled listening and therapeutic communication to strengthen the professional-patient bond and promote self-care[26].

The research results reflect the scenario within a specific time frame and at a single healthcare facility. In addition, this is a retrospective study, which prevents the assessment of late adverse effects in the population. The absence of a statistical association between therapeutic variables and the occurrence of the main toxicities may reflect both the limited sample size and the retrospective nature of the study, which reduces the ability to establish causal relationships.

These results, although relevant, should be interpreted with caution and reinforce the urgency of expanding multicenter, prospective investigations that incorporate analysis of late toxicities intrinsic to cancer therapy for gynecological cancers to provide a comprehensive understanding of their potential effects in this population.

CONCLUSION

The sociodemographic profile of patients who underwent teletherapy... showed a predominance of women aged 36 to 65 years. In terms of family income, most of the population earned less than three times minimum wage and has low educational attainment. These last two aspects highlight the need for health promotion policies aimed at the most vulnerable groups.

Regarding staging, there was a higher frequency of more advanced disease stages, namely IIIC1, IIB, IIIB, and IIIC2. This scenario may be related to the inefficiency of primary and secondary care, whose strategy is the screening and early diagnosis of gynecological cancer. Awareness campaigns, effective public policies, and support programs for at-risk groups are necessary to reduce the incidence of this specific type of cancer.

Regarding adverse effects, the most prevalent toxicity was Grade 0 radiodermatitis, although this symptom is not classified as tissue damage. Regarding adverse effects on the gastrointestinal system, the most frequent toxicity was diarrhea; in the genital system, the most prevalent was vaginal discharge; and in the urinary system, the only toxicity was dysuria.

The results of the study can help guide the multidisciplinary team in patient care and management, based on the identification of the toxicity profile of women undergoing radiotherapy. The nursing team and radiological technicians are responsible for daily patient care and contact during radiotherapy and must provide quality patient-centered care.

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PREVALENCE OF ACUTE TOXICITY IN GYNECOLOGICAL BRACHYTHERAPY AT A REFERENCE CENTER IN ONCOLOGY

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