Original article

Hospital costs of cervical cancer and Law 12.732/2012

Custos hospitalares do câncer do colo do útero e a Lei 12.732/2012

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Abstract

Objective: to analyze the applicability of Law 12,732 and its relationship with the mortality rate and hospital costs in the treatment of patients with cervical cancer in Brazil from 2013 to 2022. **Materials and Methods:** retrospective, descriptive and quantitative longitudinal study, with data from the Health Information Systems, Ministry of Health. **Results:** the cost of hospital admissions for the treatment of this cancer was R$ 350,662,650.15. In the first five years of application of Law 12,732, most women began treatment for cervical cancer 60 days after diagnosis. Comparing Brazilian regions, 60.1% of women in the South region were able to start treatment for this cancer within the first 60 days after diagnosis, as opposed to 30.5% of women residing in the North region of the country. The states that started treatment as required by law had a lower mortality rate compared to those that started after the recommended period. **Conclusion:** it is necessary to define strategies to guarantee effective access for women suspected of having this neoplasm to diagnosis and treatment as early as possible in order to guarantee better chances of cure and a lower death rate.
Keywords: Cervical cancer. Mortality. Hospital internment.

Resumo

Objetivo: analisar a aplicabilidade da Lei 12.732 e sua relação com a taxa de mortalidade e os custos hospitalares no tratamento das pacientes com câncer do colo do útero no Brasil no período de 2013 a 2022. **Materiais e Métodos:** estudo longitudinal retrospectivo, descritivo e quantitativo, com dados dos Sistemas de Informações em Saúde, Ministério da Saúde. **Resultados**: o custo das internações hospitalares para o tratamento deste câncer foi de R$ 350.662.650,15. Nos primeiros cinco anos de aplicação da Lei 12.732, a maioria das mulheres iniciaram o tratamento do câncer cervical após 60 dias do diagnóstico. Comparando as regiões brasileiras, 60,1% das mulheres da região Sul conseguiram iniciar o tratamento deste câncer nos primeiros 60 dias após o diagnóstico, em oposição a 30,5% das mulheres que residem na região Norte do país. Os estados que iniciaram tratamento, conforme dita a lei, tiveram taxa de mortalidade menor em comparação àqueles que iniciaram após o período preconizado. **Conclusão:** é necessário definir estratégias para garantir o efetivo acesso das mulheres com suspeita desta neoplasia ao diagnóstico e tratamento o mais precoce possível a fim de lhes garantir melhores chances de cura e menor taxa de óbito.
Palavras-chave: Câncer do colo do útero. Mortalidade. Internação Hospitalar.

Introduction

In 2020, cervical cancer (CC) was the fourth most common cancer in women worldwide, with an estimated 604,000 new cases diagnosed and 342,000 deaths due to the disease. In Brazil, excluding non-melanoma skin tumors, this cancer is the third most frequent occurrence in women, accounting for 6,627 deaths[1].

The main prognostic factor in women with CC is the stage at diagnosis, being the treatment based on surgery, radiotherapy, chemotherapy or a combination of these therapeutic strategies. Recognizing the importance of starting early treatment in reducing cancer mortality, in 2012, Law 12.732[2] was instituted, also known as the 60-day Law, that guarantees the right of patients with malignant neoplasms to begin their first treatment in the Unified Health System (SUS) within a maximum period of 60 days after the date of diagnosis. This determination was changed in 2019 by Law N 13.896[3], which established a maximum period of 30 days for the performance of tests when the main diagnostic hypothesis is malignant neoplasm.

In addition to the human losses caused by cancer, there is a great financial cost for both women and society and the State worldwide. Women of productive age suffer temporary or permanent loss of their working capacity, resulting in the absence from formal or autonomous work[4]. In Brazil, in addition to having their clinical and/or surgical treatment funded by the SUS, women are supported by the benefit of sickness assistance or continuous benefit in the amount of 1 (one) monthly minimum wage through Social Security[5].

In the current scenario of health research in Brazil, there is a notable gap of nationwide studies that investigate the financial impact of CC treatment. Despite the prevalence of this disease and its relevance in public health, few studies have been devoted to analyzing in detail the applicability of Law 12.732/2012 and its association with hospitalizations, costs and mortality rate.

In this context, the objective is to analyze the applicability of the 60-day Law and its relationship with the mortality rate and hospital costs in the treatment of patients with cervical cancer in Brazil from 2013 to 2022.

Materials and Methods

This is a retrospective, descriptive and quantitative longitudinal study with data obtained from the Health Information Systems (HIS) maintained by the Ministry of Health (MoH): (1) Hospital Information System of the Unified Health System (HIS/SUS)[6]; (2) Brazilian Oncology Panel[7] and (3) Integrator Hospital Registry of Cancer (HRC)[8]. In July 2023, the cases of cervical cancer (code C53),

according to the 10th revision of the International Classification of Diseases (ICD-10)[9], were collected from women aged between 25 and 64 years old, depending on the Region of residence, including the period from June 2013 to December 2022. There was no sample calculation because a time space of the occurrence of cases has been delimited.

Data were typed, organized and analyzed using the statistical software Statistical Package for the Social Sciences for Windows (SPSS®), version 23.0. The variables investigated were described by their absolute frequency distribution and percentage. Then, the univariate analysis was performed between the dependent variable, treatment time and each independent variable, mortality rate, average stay in days, total value of hospitalizations and average Hospital Admission Authorization (HAA) value, adopting chi-square test. For this, the dependent variable was dichotomized into "up to 60 days" and "after 60 days". The independent variables were categorized by the lower limit of the confidence interval, estimated at 95% and significance level of p≤0.05.

Ethical care

Because it is a study conducted with secondary data from the SIS, the study was exempted from submission to a Research Ethics Committee, with due observation of the ethical aspects contained in two resolutions of the National Health Council: CNS N. 466 of 12 December 2012 and CNS N. 510 of 7 April 2016.

Results

In the period from 2013 to 2022, the HRC Integrator consolidated a total of 128,547 cases of cervical cancer in Brazil, with the highest number of cases concentrated in 2018. The highest incidence was in the Southeast Region with 37.7% of the total number of cases, followed by the Northeast (29.9%), South (17.9%), North (9.7%) and Midwest (4.8%).

Regarding the demographic characteristics, the most affected age group was 35 to 44 years old in all Regions of Brazil with 32%, followed by the age from 45 to 54 years old with 25%, women between 25 and 34 years old 5% and finally women aged between 55 and 64 years old make up 19.5% of the cases.

Regarding schooling, 45.7% of women have elementary school and 20.7% high school education. It should be noted that 21.7% of these cases had this information omitted at the time of registration. The same omission occurred with records regarding marital status, in which 27% of women did not provide this information, were not questioned or their answers were not recorded. In

addition, 37.2% and 31.9% declared themselves divorced and/or single and married and/or in a consensual union, respectively. Regarding tobacco consumption, the omission of this information is repeated in 47% of cases, about 34% denied consumption and 10.2% and 8.6% declared themselves as smokers and ex-smokers, respectively. Regarding alcohol consumption, 33.6% of the women denied drinking and in 52.2% of the cases this information was not recorded.

Regarding the clinical aspects, 23.5% women denied a family history of cancer, and in 55.3% of cases this information was not recorded and another 21.1% stated a family history of neoplasms. Regarding the staging at the time of diagnosis, 20.6% were classified in Stage 0, and another 19.7% in Stage III. As for the first treatment received, 42.2% of the women underwent surgery and 41.1% started with chemotherapy.

Overall, the cost of hospital admissions for women with cervical cancer in the period studied was R$ 350,662,650.15, with the Northeast Region accounting for 35% of this amount (R$ 122,777,498.20), followed by the Southeast Region with 32.6% (R$ 114,414,579.58). The average value of HAA was R$ 1,978.84, with the Northeast Region having the highest value assigned to each HAA (R$ 2,516.65) and the Southeast Region with the lowest value (R$ 1,665.30). The average number of days that each woman was hospitalized was 5.3 days, lower average was found in the South Region (4.5 days) and higher average in the North Region (7.6 days). In relation to mortality, the total number of deaths from this neoplasm was 17,501, highlighting the Southeast Region with 6,888 deaths and, when comparing the mortality rate, which was 9.89%, the North Region reached a higher rate of 14.38% and the South Region presented a lower rate with 7.39%.

The annual distribution of cases in Brazil, according to the two categories of delay time (days) for the start of treatment of CC, is recorded in Figure 1. It is noted that in the first five years of application of the 60-day most women started cervical cancer treatment after 60 days of diagnosis. Only from the year 2017, there was an increase in the number of cases that began treatment as recommended by the Law, but it still represents less than 50% of women. As in the other public databases, in 20,672 cases the time of beginning of treatment was not recorded and an alarming increase in this sub-registration over the period studied is highlighted.

Figure 1. Distribution of the time interval between diagnosis and initiation of cervical cancer treatment in Brazil from 2013 to 2022.

●up to 60 days ★ more than 60 days ▲ no information
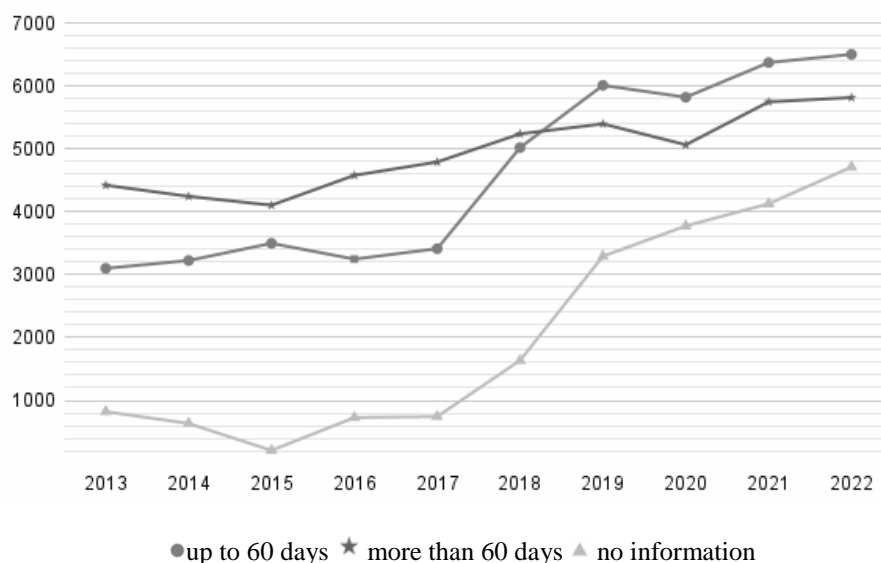
Source: Oncology Panel Brazil.

In relation to the application of Law 12.732/12 between the five Regions of Brazil, it is notable the discrepancy between the time of beginning treatment in the North and South Regions, in which 60.1% of women from the South Region were able to start treatment for this cancer within the first 60 days after diagnosis, as opposed to 30.5% of women living in the North Region of the Country. In the other Regions, there was a homogeneous distribution among them, although only about half of the numbers of women benefited from the Law (Table 1).

Table 1. Time interval between diagnosis and initiation of cervical cancer treatment in Brazil from 2013 to 2022 by region.

Region	Up to 60 days		More than 60 days		
	n	%	n	%	Total
North	2,889	30.5	6569	69.5	9,458
Northeast	14,129	49.1	14,631	50.9	28,760
Midwest	3,616	51.0	3479	49.0	7,095
Southeast	14,890	45.8	17628	54.2	32,518
South	10,685	60.1	7,098	39.9	17,783
No information					20,672

Source: Oncology Panel Brazil.

The results of the association analysis between the time interval from diagnosis to treatment initiation and the Table 2. The Brazilian States in which women began CC treatment after 60 days had a higher mortality rate compared to those who started treatment within the time prescribed by Law 12.732/12 (p<0.05). Another association concerns the mean value of HAA: States with treatment start time greater than 60 days had a lower value of HAA than those States that started treatment early (p<0.05). There was no statistically significant association with the average stay and total value of expenditure variables.

Table 2. Univariate analysis between the start of treatment after cervical cancer diagnosis and the variables mortality rate, average length of stay, total amount spent and average HAA value in Brazilian states from 2013 to 2022.

Variable	Initiation of treatment (in days)			
	Up to 60 days	More than 60 days		
Mortality rate (average)	**n (%)**	**n (%)**	**95%CI**	**P value***
≤ 9.5	8 (66.7)	4 (33.3)	1.047-28.879	**0.038**
9.6 or more	4 (26.7)	11 (73.3)		
Average length of stay (days)				
≤ 5.4	7 (63.6)	4 (36.4)	0.761-19.468	0.096
5.5 or more	5 (31.2)	11 (68.8)		
Total amount spent				
≤ R$ 8,649,956.42	5 (35.7)	9 (64.3)	0.102-2.230	0.343
R$ 8,649,956.43 or more	7 (53.8)	6 (46.2)		
Average HAA value				
≤ R$ 1,752.51	1 (11.1)	8 (88.9)	0.008-0.781	**0.014**
R$ 1,752.52 or more	11 (61.1)	7 (39.9)		

HAA: authorization of hospitalization. * Significant chi-square test p≤0.05.

Discussion

The human papillomavirus (HPV) is a key risk factor for cervical cancer in approximately 99.7% of tumors[10]. The highest risk of HPV infection is associated with the period of increased metaplastic activity, which occurs during puberty and first pregnancy, reducing after menopause. Infection with the virus is more frequent among young sexually active women, aged between 18 and 30 years old. After age of 30, there is a significant reduction in the prevalence of infection. However, cervical cancer is more prevalent in women over 35 years old, which indicates that the infection may have occurred earlier, with slow progression to the development of neoplasm[11].

This study pointed out the age group with the highest CC involvement between 35 and 44 years old. A survey conducted with women in the State of Bahia reflected this national finding, whose age range was also 35 to 44 years old[12]. Researchers from Korea[13] found a higher incidence of this

cancer in women in the same age group, with an increasing incidence for the age group 30 to 39 years old and a decreasing trend in 40 to 44 and 50 to 54 years old, but differs from another studies[14] in that the average age of 51 years old predominated.

The association of the risk of contracting CC with the level of schooling suggests that the lower the educational level of the population, the greater the risk of developing neoplasia. In this study, the majority of women affected had only elementary school education, similar to the study mentioned above in Bahia[12] and a survey conducted in Mexico City in which 77% of women did not complete high school. This result may be associated with greater involvement in self-care by people with higher levels of education, due to their better understanding of the health-disease process, greater knowledge and access to health services, as well as better social conditions[15].

In this epidemiological study, 18.8% of the women Stated to be smokers or ex-smokers. In recent years, the relationship between smoking and cancer has increased significantly, especially in organs such as the oral cavity, pharynx, esophagus, stomach, colon, rectum, liver, pancreas, larynx, lungs, bronchi, trachea, kidneys, bladder, urinary tract and cervix, besides acute myeloid leukaem[16]. In smokers, cervical mucus presents greater mutagenic potential, transmitting a direct link with damage to the DNA of women with cervical cancer. An integrative review[17] published in 2021 raised the main risk factors associated with cervical neoplasia, with smoking present in several studies, highlighting a study in which this habit was present in 45,8% of women diagnosed with this cancer with strong association to the histological type squamous cell carcinoma.

Surgery was the first treatment modality indicated for women in this study. It corroborates with findings from another Brazilian study[18] in which this treatment modality was also the first and occurred early, that is, before 60 days. According to the authors, this scenario can be explained by the greater access to this type of treatment, as a result of the qualification of some general hospitals for performing oncological surgeries. This usually results in a shorter wait time at these establishments, compared to the high complexity. In addition, we emphasize that, in some cases, the definitive diagnosis is made after the first intervention, when samples are collected during surgery and submitted to histopathological analysis to confirm the diagnosis.

Accurate estimates of the cost of cancer treatment are crucial for economic assessments, policy decisions and forecasting future cancer-related medical care expenditures. From an economic perspective, the costs of hospitalization for the treatment of women with this neoplasm are aligned with the rates of hospitalizations by Region in Brazil, highlighting the Northeast and Southeast as the Regions that present the highest expenses[19].

The costs of hospital admissions in Brazil due to CC amounted, over these 10 years, to R$ 350,662,650.15 and the average value of HAA was R$ 1,978.84, which is equivalent to approximately US$ 72 million and US$ 405 respectively. Research conducted in a tertiary hospital in Beijing, China, raised the costs of treatment for this cancer from 2011 to 201620. During this period, the average value of hospitalizations was RMB 29,509.1, which is equivalent to approximately US$ 4 thousand. Estimated costs related to diseases, including cervical cancer, tend to be lower in Brazil compared to developed countries. This difference can be attributed to the limitation in access and use of health services, lower average costs of medical care and lower family income[21]. In the decade studied, the average number of days per hospitalization was 5.3 days. In a study carried out in Spain in 2018, this time was 6.6 days[14].

Cervical cancer occupies a prominent place among the oncological diseases in females. In the analysis of deaths occurred during hospital admissions due to cervical neoplasia, 17,501 deaths were recorded over 10 years. A Brazilian study[22] that evaluated the hospital mortality associated with this neoplasia between 2012 and 2017 found 13,358 deaths in 5 years, representing 10.6% of women hospitalized with this pathology. The analysis was restricted to women with cervical and internal cancer, but it is essential to account for cases of lack of access to hospital care, either due to the unavailability of beds or the difficulty of the patient in seeking treatment

Law N. 12.732/2012 guarantees that every patient has the right to perform the first treatment within 60 days after the diagnosis of cancer in SUS.

The period begins from the dispatch of the report attesting to the disease and ends on the day of the first treatment, that is, when the patient undergoes the surgical procedure or the first session of chemotherapy or radiotherapy, as indicated for each case. Several sociodemographic factors are related to the delay in the beginning of treatment, highlighting structural challenges in the health system. Black people, with low socioeconomic and educational status, living in rural areas or far from urban centers and without access to health insurance tend to face greater difficulties in obtaining an early diagnosis and starting treatment of various neoplasms[18].

Up to 2017, the proportional distribution of cases that were treated within 60 days remained practically stable and lower than those that were not treated within this same period. From 2018, there was an increase of 1.5 times, rising gradually and favorably. All cases of neoplasms registered in the Oncology Panel from 2013 to 2020 were analyzed and it was found that 51.3% of women started treatment in a timely manner, with surgery being the first modality.[18]

When analyzing the CCU specifically, another national study[23] identified that 65% of women started treatment after the 60-day Law, ratifying other national studies. In Taiwan[24], between 2005 and 2010, 9,081 women were diagnosed with this neoplasm and only 3.82% did not start treatment within the time recommended by this Country, which is 4 months. Another highlight is that in 2005, this metric was 6.46% and in 2010 it fell to 2.48%.

This study showed an association between delay in the beginning of treatment and mortality. The Brazilian States in which women started treatment after 60 days had a higher mortality rate compared to those who began treatment within the established time. A meta-analysis[25] conducted with data from 34 studies (N=1,272,681 patients) investigated the prevalence of the seven most common cancers globally, including cervical cancer (CC). The results showed that each four-week delay between diagnosis and start of treatment or between the end of one treatment and the beginning of the next was associated with a 6 to 8% increase in the probability of death. In addition, delays of 8 to 12 weeks increased mortality by 17% and 26%, respectively. These findings highlight the critical importance of time in cancer treatment and its significant impact on the population.

States that started treatment of women with cervical neoplasia after 60 days of diagnosis had lower average HAA cost. In the literature, no studies were found that made an association between the time of treatment start and hospital costs. International research[26,27] show that the consumption of resources for cancer patients is higher during the initial phase of treatment and in the terminal stage before death, because in the first year after diagnosis patients are submitted to the most aggressive primary treatment and have higher mortality. However, new studies are needed to better elucidate this phenomenon.

Conclusion

This study highlighted important gaps in the applicability of the 60-day Law in Brazil, highlighting the discrepancy between what is provided for by legislation and the reality experienced by many patients with cervical cancer between 2013 and 2022. Data analysis revealed that, despite advances since 2017, less than half of the patients started treatment within the established time frame, with strong Regional variations. The South and Southeast Regions stood out with greater adherence to the Law, while the North Region was the most affected, presenting the highest rates of delay and associated mortality.

The significant relationship between delayed treatment initiation and mortality reinforces the importance of rapid and effective actions in the fight against cervical cancer. States where treatment

was started after 60 days had higher mortality rates, pointing to the negative impact of delay on patients' prognosis. In addition, the results showed that the average cost of HAA was lower in States with greater delay in treatment, suggesting possible limitations in access and use of health services at more advanced stages of the disease.

Greater equity in access to cancer treatment is needed in Brazil, with special attention to the North and Northeast Regions. To ensure effective implementation of the 60-day Law, improvements are needed in the organization of health services, greater efficiency in early diagnosis and the response capacity of treatment units. Such measures are essential to reduce Regional inequalities, improve patient survival and optimize the financial resources invested in the treatment of this neoplasm.

Authors' contributions

Sabrina Gonçalves Silva Pereira, Marcelo José da Silva de Magalhães, Árlen Almeida Duarte de Sousa and Alex Aparecido Pereira: Conception and design of the research; data collection; analysis and interpretation of the data; manuscript writing; Critical review of the manuscript regarding its intellectual content and final presentation. The authors approved the final version of the manuscript and declared themselves responsible for all aspects of the work, including ensuring its accuracy and integrity.

Conflict of interest

The authors declare that there are no conflicts of interest.

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