

The 60-Days Law: Reality of Timely Treatment in the Analysis of a Series of Colorectal Cancer Cases

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Lei dos 60 Dias: Realidade do Tratamento Tempestivo na Análise de uma Série de Casos de Câncer Colorretais

Ley de 60 Días: Realidad del Tratamiento Oportuno en el Análisis de una Serie de Casos de Cáncer Colorrectal

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ABSTRACT

Introduction: The Law 12,732/12 determines that the first oncological treatment occurs within 60 days after diagnosis. **Objective:** To verify the compliance with the law in patients with colorectal cancer (CRC) treated at “Hospital Evangélico de Cachoeiro de Itapemirim (HECI)”. **Method:** Cross-sectional retrospective study with data collected from “Sistema de Registro Hospitalar de Câncer (SisRHC HECI)” in the period 2010-2017 to identify the first treatment after diagnosis. A descriptive analysis was performed and the chi-square test was utilized to evaluate the difference in time between diagnosis, ≤ 60 days or > 60 days and the first oncological treatment. **Results:** 585 cases of CRC were identified, mostly in males (52.8%), stages III and IV (60%), located in the colon (65%), aged between 51 and 80 years (70.5%) and 71% received their first treatment within 60 days. In the univariate analysis, cases aged ≤ 50 years and with tumors located in the colon were more likely to receive the first treatment within 60 days ($p < 0.05$). The average time between the date of the histopathological report and the first consultation was 51.06 days and the average time between the first consultation and the first treatment was 30.10 days. **Conclusion:** Almost a third of patients did not receive the first treatment as determined by the law. Younger patients with a tumor located in the colon were more likely to receive the first treatment within 60 days. The time for the first consultation with an expert at a High Complexity Oncology Unit (Unacon) seems to be the main factor in delaying the first treatment. **Key words:** neoplasms; epidemiology; delayed diagnosis; time-to-treatment; public policy.

RESUMO

Introdução: A Lei 12.732/12 determina que o primeiro tratamento oncológico ocorra em até 60 dias após o diagnóstico. **Objetivo:** Verificar o cumprimento da lei em pacientes com câncer colorretal (CCR) tratados no Hospital Evangélico de Cachoeiro de Itapemirim (HECI). **Método:** Estudo transversal com coleta de dados retrospectivos do Sistema de Registro Hospitalar de Câncer (SisRHC HECI) no período de 2010 a 2017 para identificar o primeiro tratamento após diagnóstico. Foi realizada análise descritiva e utilizado o teste qui-quadrado para avaliar a diferença do tempo entre o diagnóstico, ≤ 60 dias ou > 60 dias, e o primeiro tratamento oncológico. **Resultados:** Foram identificados 585 casos de CCR, a maioria em homens (52,8%), classificados em estádios III e IV (60%), localizados no cólon (65%), com idade entre 51 e 80 anos (70,5%), e 71% receberam primeiro tratamento em até 60 dias. Na análise univariada, os casos com idade ≤ 50 anos e com tumores localizados no cólon tiveram maior probabilidade de receber o primeiro tratamento em até 60 dias ($p < 0,05$). O tempo médio entre a data do laudo histopatológico e a primeira consulta foi de 51,06 dias e o tempo médio entre a primeira consulta e o primeiro tratamento foi de 30,10 dias. **Conclusão:** Quase um terço dos pacientes não recebeu o primeiro tratamento conforme preconizado pela lei. Pacientes mais jovens e com tumor localizado no cólon tiveram probabilidade maior de receber o primeiro tratamento em até 60 dias. O tempo para a primeira consulta com especialista da Unidade de Assistência de Alta Complexidade em Oncologia (Unacon) parece ser o principal fator de atraso do primeiro tratamento.

Palavras-chave: neoplasia; epidemiologia; diagnóstico tardio; tempo para o tratamento; política pública.

RESUMEN

Introducción: La ley 12.732/12 determina que el primer tratamiento oncológico debe ocurrir dentro de los 60 días posteriores al diagnóstico. **Objetivo:** Verificar el cumplimiento de la ley en pacientes con cáncer colorrectal (CCR) atendidos en el Hospital Evangélico de Cachoeiro de Itapemirim (HECI). **Método:** Estudio transversal con recolección de datos retrospectivos del Sistema de Registro Hospitalario de Câncer (SisRHC HECI) en el período 2010-2017 para identificar el primer tratamiento después del diagnóstico. Se realizó un análisis descriptivo y se utilizó la prueba de ji cuadrada para evaluar la diferencia en el tiempo entre el diagnóstico, ≤ 60 días o > 60 días, y el primer tratamiento oncológico. **Resultados:** Se identificaron 585 casos de CCR. La mayoría eran hombres (52,8%), estadios III e IV (60%), localización en colon (65%), edades entre 51 y 80 años (70,5%) y el 71% recibió su primer tratamiento dentro de los 60 días. En el análisis univariado, los casos de edad ≤ 50 años y con tumores localizados en el colon tuvieron más probabilidades de recibir el primer tratamiento a los pocos días ($p < 0,05$). El tiempo promedio entre la fecha del informe histopatológico y la primera consulta fue de 51,06 días y el tiempo promedio entre la primera consulta y el primer tratamiento fue de 30,10 días. **Conclusión:** Casi un tercio de los pacientes no recibió el primer tratamiento recomendado por la ley. Los pacientes más jóvenes con un tumor localizado en el colon tenían más probabilidades de recibir el primer tratamiento dentro de los 60 días. El momento de la primera consulta con un especialista de la Unidad de Atención Oncológica de Alta Complejidad (Unacon) parece ser el principal factor en el retraso del primer tratamiento. **Palabras clave:** neoplasias; epidemiología; diagnóstico tardío; tiempo de tratamiento; política pública.

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INTRODUCTION

Cancer is one of the main public health problems of the twenty first century worldwide. The disease is at the center of the debates on medicine and public health in Brazil^{1,2} due to its rising epidemiologic impact and necessity of expanding the scope of the actions for better control by the National Health System (SUS).

It is the second cause of death by disease in the world^{1,3} with high global mortality. In Brazil, the non-adjusted proportional mortality rate for 2021 was 11.9 for each 100 thousand deaths in men and 13.5 for each 100 thousand deaths in women⁴.

The morbimortality of this disease, restricted for many years to a curative instead of preventive approach, increased along the twentieth century. Public health oncology policies were created shortly before the implementation of the Retirement and Pensions Funds, specifically in 1921 in the State of São Paulo with the first action focused to cancer⁵. In the following years, medical militancy increased progressively, and a substantial portion of the society pushed for solutions of impact on public health as the inclusion of oncologic patients⁵. After the implementation of SUS enforced by Law 8,080 of 1990⁶, the National Cancer Institute (INCA) became the coordinator of cancer prevention strategies.

Much has been discussed on how to reduce cancer morbimortality in the last decades, but early diagnosis through population screening and access to oncologic treatment have been the most effective strategies. In 2012, in an attempt to ensure the timeliness of assistance to patients with any diagnostic of cancer, the Legislative passed, and the President sanctioned Law 12,732⁷ – the 60-days law –, widely known in Brazil as one of the strategies which are part of public policies to reduce the disease's toll.

As structured screening for early diagnosis of colorectal (CRC) cancer in Brazil⁸ is not performed, the timely treatment of the cases diagnosed becomes essential to reduce its burden. The reality of the oncologic specialized services should be known to evaluate whether the current legislation – the 60-days law – is being complied with. The present study attempts to respond to the following question: “Have the patients diagnosed with CRC assisted at “*Hospital Evangélico de Cachoeiro de Itapemirim (HECI)*” been receiving the first oncologic treatment within 60 days?”.

METHOD

Quantitative, longitudinal, retrospective study from 2010 to 2017 with data collected from “*Sistema de Registro*

Hospitalar de Câncer (SisRHC)/HECI” (hospital-based cancer registries) a reference in oncology for the South region of the Espírito Santo State.

The sample participants were patients registered at SisRHC/HECI whose first study visit occurred between 2010 and 2017. 6,962 new cancer cases were identified, 3,690 in men and 3,272 in women.

Cases diagnosed with CRC according to the International Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10)⁹ from C18.0 to C20.9 – total of 676 new cases – have been selected. Patients registered at SisRHC/HECI, older than 18 years of age, both sexes with confirmed diagnosis by histopathology of malignant neoplasms who attended the first oncologic visit at HECI (analytical cases) were enrolled.

Patients without anatomopathological diagnosis and date of the first oncologic treatment at HECI oncology and those who initiated the first oncologic visit elsewhere and were later transferred to HECI (non-analytical cases) were excluded. 585 analytical cases remained after exclusion criteria were applied.

The variable age was grouped in 18-50 years, 51-80 years and above 80 years. The age range of 50 years was selected since the adults within this age range are considered “young adults” for CRC diagnosis. The age range of the pyramid of “*Instituto Brasileiro de Geografia e Estatística (IBGE)*” ends in 80 years. In addition, most studies exclude patients older than 80 years.

The data were collected from SisRHC and registered in a file with the following information: a) sociodemographic profile: sex (male, female), age at the first visit (18-120 years), race, history of alcohol and tobacco use, education level; b) location of the primary tumor according to ICD-10⁹.

The cases of ICD C18 and C19 were grouped and analyzed together because they share the same epidemiological aspects, treatment and prognosis. The staging of different types of cancer was based in the seventh¹⁰ and eight¹¹ editions of TNM Classification of Malignant Tumors published in 2010 and 2016 respectively. Time range for CRC oncologic treatment was counted from the date of the pathological diagnosis and the date of the first oncologic treatment received at HECI. For analysis purpose, the interval since the histopathological diagnosis and the first oncologic treatment was divided in two moments:

Time 1: time since the diagnosis confirmed by histopathology and the first visit to the oncologist.

Time 2: time since the visit to the oncologist at the High Complexity Oncology Unit (Unacon) and the first oncologic treatment.

On Time 1, 139 cases were discarded since the first visit at Unacon occurred before the histopathology. The reason is because Unacon receives patients with confirmed histopathology diagnosis and patients with high suspicion of neoplasms as colonoscopy with vegetation lesion submitted to biopsy and waiting histopathology, tomography with liver metastases whose investigation revealed colorectal neoplasm, patients admitted at the emergency with colorectal neoplasm obstruction among others. On Time 2, 583 cases were analyzed. Two cases were excluded because there was no referral for oncologic treatment.

Sixty days was the upper limit of time acceptable. Time range between the diagnosis and the first visit to an oncologist was called Time 1 and time range between the visit to an oncologist (at Unacon) and the first oncologic treatment, Time 2. This division had the objective to identify whether the delay of the beginning of the treatment was due to difficulty of access to the oncologist (at Unacon) or post-visit internal problems at Unacon. It is believed that this procedure is an indirect manner to evaluate the enforcement of the 60-days law in patients who attended the first oncologic treatment at HECI from 2020 to 2017.

Inductive or inferential statistical analysis utilized the software BioEstat 5.3 for univariate tests, with level of significance of $p < 0.05$, through Fisher's chi-square or exact tests with confidence interval of 95% (CI 95%) for all the analyzes based in the frequency table.

The present study is part of an initial project titled "*Acesso ao Tratamento Oncológico de Pacientes Atendidos em Hospital de Referência da Região Sul-Capixaba*" submitted to and waived from approval by the Institutional Review Board (IRB) of "*Escola Superior de Ciências da Santa Casa de Misericórdia de Vitória (Emescam)*", report number 3,760,959 in compliance with Directive 510/2016¹² of the National Health Council.

RESULTS

Of the 585 cases analyzed, 117 patients (20% of the cases) were in the age-range 18-50 years old (Table 1). 95 patients of the 20%, equivalent to 81%, received the first oncologic treatment within 60 days (Table 2). Table 1 presents the population of patients investigated divided by age range (18-50 years; 51-80 years and older than 80 years) and according to the most relevant clinical and demographic characteristics.

Globally, in the period investigated, 71% of the patients with CRC received the first oncologic treatment within 60 days after the diagnosis. Table 2 presents the results of the first global oncologic treatment and according to the socioeconomic variable analyzed.

The result of the comparison among clinical variables and time to begin the first treatment is portrayed in Table 3. ICD C18 and C19 (topographic location of the colon) had the highest occurrence of ≤ 60 days.

No significant differences were found after analyzing the beginning of the first treatment according to the type of treatment received as shown in Table 4.

The mean time between the date of the diagnosis (histopathology) and the first consultation with the oncologist at Unacon was 51.06 days for 446 cases. The mean time between the first consultation with the oncologist at Unacon and the date of the first treatment was 30.10 days. In the current study, 583 cases were eligible. Considering the 585 cases, the mean time between the histopathology-based diagnosis was 60.48 days.

DISCUSSION

Cancer is a high-incidence disease in the world and nationally. 19.3 million new cases are estimated worldwide. In Brazil, 704 thousand new cases are anticipated for each year of the triennium 2023-2025³. Also, it is a high mortality disease, it is the second cause of death by disease in the world and in Brazil. For this reason, cancer is a world concern and is listed in the political agenda of great part of the countries, mainly in the twentieth first century^{1,4}.

The 60-days law sanctioned by the President in 2013 became widely known in Brazil because it is a milestone in ensuring access to oncologic treatment; as law-enforced, the patient should receive the first oncologic treatment within 60 days at the most, avoiding delays in the beginning of the treatment. However, the law does not warrant its implementation, studies evaluating the time since diagnosis and beginning of oncologic treatment should be conducted in oncologic treatment sites in many Brazilian regions to evaluate its effectiveness.

The present study was carried out at an oncology treatment site located in the South region of the State of Espírito Santo (Unacon with radiotherapy) specialized in CRC. The site provides care to the State's South Macroregion with 26 municipalities and a population of 693,396 individuals according to the Regional Master Plan of 2016¹³. The patients are referred to Unacon through the municipality scheduling system (SisReg) or at the oncology service by the own patient or medical referral to oncology or presenting a confirmatory test that justifies the oncology assistance (high suspicion of neoplasm or confirmatory histopathology). The decision to investigate CRC is its high incidence and high mortality.

Upon analysis of the 585 charts of the patients enrolled, 71% received the first oncologic treatment

Table 1. Patients analyzed by age-range according to clinical and demographic characteristics

585 patients Total	Age range 18-50 years 117		Age range 51-80 years 413		Age range > 80 years 55	
	Percent 20.00%		Percent 70.59%		Percent 9.40%	
Variable	N	%	N	%	N	%
Male	61	10.42%	218	37.26%	30	5.12%
Female	56	9.57%	195	33.33%	25	4.27%
White	53	9.05%	198	33.84%	37	6.32%
Black/Brown	50	8.54%	170	29.06%	12	2.05%
Yellow	0	0.00%	2	0.34%	0	0.00%
No information	14	2.39%	43	7.35%	06	1.02%
Alcohol use						
Ever	69	11.79%	237	40.51%	29	4.95%
Yes/Ex-user	33	5.64%	99	16.92%	7	1.19%
No information	5	0.85%	29	4.95%	5	0.85%
Tobacco use						
Ever	76	12.99%	206	35.21%	21	3.58%
Yes/Ex-user	29	4.95%	145	24.78%	15	2.56%
No information	3	0.51%	23	3.93%	5	0.85%
Location (ICD-10)						
C18.0 to C19.9	78	13.33%	267	45.64%	35	5.98%
C20.0 to C20.9	39	6.66%	146	24.95%	20	3.41%
Staging						
1	9	1.53%	32	5.47%	4	0.68%
2	21	3.58%	76	12.99%	12	2.05%
3	45	7.69%	158	27.00%	22	3.76%
4	28	4.78%	95	16.23%	6	1.02%

Caption: ICD-10 = International Classification of Diseases and Related Health Problem⁴⁹.

in until 60 days. Nearly one third of the patients did not receive timely oncologic treatment in until 60 days and this is a high number if compared with the data published by INCA's *Observatório de Oncologia* (Oncology Observatory) whose global rate was 20.4% for 2009-2015¹⁴.

It was possible to conclude from the analysis of the study variables that patients aged ≤ 50 years and patients with colon tumor (ICD C18 and C19) had more possibilities of receiving the first treatment in until 60 days. These data are similar to another study which indicates that the beginning of the treatment for individuals older 50 years was delayed if compared with those diagnosed with CRC younger than 50 years⁸. The possible justifications for this finding are:

a) Younger patients usually have no locomotion issues and are less dependent to seek medical care. Older patients need help from relatives to schedule visits and transportation that quite often is provided by the health services with previous scheduling or even by family members, friends and neighbors;

b) Younger patients are more knowledgeable of information found in social media, understand best the disease, its symptoms and suspicion of CRC and seek medical care as opposed to older groups who more than often hide the symptoms to spare the family and continue working, ignoring the severity and aggravation of the disease;

c) Younger patients have less comorbidities and preparation for eligible surgery is faster, requiring only preoperative tests and consultation with anesthesiologist and cardiologist, as opposed to older groups who need additional and more complex tests pre-operation as doppler and ergometric test delaying the beginning of the treatment.

These data are similar to the study by Lima et al.¹⁵ who investigated factors associated with time to begin the treatment of colorectal cancer in Brazil (2006-2015).

Patients with colon tumors need less complementary exams as recommended by the National Comprehensive Cancer Network (NCCN)¹⁶ and less professionals for decision taking about the first treatment compared with rectum cancer.

Table 2. Analysis of the socioeconomic variables in relation to time between the anatomopathological diagnosis and first oncologic treatment received: ≤ 60 days or > 60 days in patients with CRC

Variable		≤ 60 days	(%)	> 60 days	(%)	p
Total	All	417	(71.28)	168	(28.72)	
Sex	Male	225	(72.81)	84	(27.13)	0.438
	Female	192	(69.56)	84	(31.44)	
Age Range	18 to 50 years	95	(81.19)	22	(28.81)	0.028 ¹
	51 to 80 years	283	(68.52)	130	(31.47)	
	≥ 81 years	39	(70.90)	16	(29.09)	
Race	White	200	(69.44)	88	(30.56)	0.489
	Black/Brown	173	(74.56)	59	(25.44)	
	Yellow	1	(50.00)	1	(50.00)	
	No information	43	(68.26)	20	(31.75)	
Alcohol use	Ever	232	(69.25)	103	(30.75)	0.115
	Ex-user	63	(70.78)	20	(29.22)	
	Yes	41	(82.00)	9	(18.00)	
	No information	81	(72.97)	30	(26.03)	
Tobacco use	Ever	219	(72.27)	84	(26.73)	0.325
	Ex-user	96	(66.20)	49	(23.80)	
	Yes	35	(79.54)	9	(20.46)	
	No information	67	(72.04)	26	(27.96)	
Education	Illiterate	33	(63.46)	19	(35.54)	0.109
	Elementary	188	(69.88)	81	(30.12)	
	High school	65	(83.33)	13	(16.67)	
	College	27	(72.97)	10	(27.03)	
	No information	104	(69.79)	45	(30.21)	
Origin	Caparaó	58	(62.36)	35	(37.64)	0.105
	Polo Cachoeiro	286	(74.09)	100	(25.93)	
	M. Expandida Sul	66	(70.21)	28	(29.89)	
	Others	7	(58.33)	5	(41.67)	

¹ $p < 0.05$, Fisher's exact or chi-square test.

Usually, colon cancer treatment is decided and performed only by the surgeon while rectum cancer (ICD C20) requires evaluation by the surgeon, oncologist and radiotherapist most of the times; in addition, complementary exams as magnetic resonance imaging (MRI) of the pelvis for locoregional staging and computed tomography of rectum cancer for therapy planning in cases were neoadjuvant treatment as radiotherapy is prescribed, as opposed to colon cancer which does not need these procedures, which would justify the difference of time to begin the treatment for these two types of cancer.

The motives for not receiving the first treatment are multifactorial, but, actually, the time range since the anatomopathological diagnosis and the first oncologic treatment should be divided in two separate periods: the period since the anatomopathological diagnosis and the oncology consultation at Unacon (Time 1) and the period since the consultation with the oncologist at Unacon and the first oncologic treatment (Time 2), since the actions to reduce this time are different.

The mean time between the date of the diagnosis (histopathology) and the first consultation with the oncologist of Unacon was 51.06 days and the mean time since the first consultation with the oncologist at Unacon and the date of the first oncologic treatment was 30.10 days as concluded in this study where Time 1 was nearly two-fold bigger than Time 2.

CONCLUSION

Offer timely oncologic treatment is a challenge yet. Future public policies should address patients older than 50 years and those diagnosed with rectal cancer covering different periods since the diagnosis up to the first oncologic treatment performed at Unacon or Cacon considering that quite often the diagnosis is made in hospitals other than Unacon or Cacon.

The actions related to the first treatment should be made on the municipalities which refer cases to Unacon or Cacon and, in the second period, at Unacon or Cacon

Table 3. Comparative analysis of the clinical variables in relation to the time from anatomopathological diagnosis and the first oncologic treatment received: ≤ 60 days or > 60 days

Variable		≤ 60 days	(%)	> 60 days	(%)	p
Location of the tumor	ICD C18 and C19	285	(75.00)	95	(25.00)	0.009 ¹
	ICD C20	132	(64.39)	73	(35.61)	
Tumor (T)	T1	8	(72.72)	3	(27.27)	0.495
	T2	41	(73.21)	15	(26.69)	
	T3	167	(67.33)	81	(32.57)	
	T4	56	(75.67)	18	(24.33)	
	No information	145	(73.97)	51	(26.03)	
Lymph node (N)	N0	112	(64.00)	63	(36.00)	0.073
	N1	95	(73.07)	35	(26.93)	
	N2	65	(78.04)	19	(21.96)	
	No information	145	(73.97)	51	(26.03)	
Metastasis (M)	M0	244	(69.71)	106	(30.29)	0.581
	M1	26	(72.22)	10	(27.78)	
	No information	147	(73.86)	52	(25.14)	
Clinical stage (EC)	EC 0	4	(100.00)	0	(0.00)	0.189
	EC 1	32	(71.11)	13	(28.89)	
	EC 2	69	(63.30)	40	(36.70)	
	EC 3	160	(71.11)	65	(28.89)	
	EC 4	100	(77.51)	29	(22.49)	
	No information	52	(71.23)	21	(28.77)	

Caption: ICD-10 = International Classification of Diseases and Related Health Problems⁹.

¹p < 0.05 – Fisher's exact or chi-square test.

Table 4. Comparative analysis of the variables in relation to the time between the anatomopathological diagnosis and the first oncologic treatment received per type of treatment (chemotherapy, surgery or radiotherapy): ≤ 60 days or > 60 days

Variable		≤ 60 days	(%)	> 60 days	(%)	p
First treatment received	Chemotherapy	86	(70.49)	36	(29.51)	0.372
	Surgery	218	(74.14)	76	(25.85)	
	Radiotherapy	65	(67.01)	32	(33.00)	
	No information	46	(65.71)	24	(34.30)	

to speed up the process. It is evident that the first actions to be taken must reduce Time 1 to increase the proportion of patients able to receive the first oncologic treatment in until 60 days.

Only 8% of the patients were diagnosed at stage 1 and 60% were diagnosed later, at stages 3 and 4 together (Table 2). These results should prompt the urgent implementation of early diagnosis strategies and secondary prevention to reduce the negative impact of CRC on the population.

Incomplete information is one of the study limitations since the main source were SisRHC files; however, it was possible to respond to the main study question, the identification of the percent of patients assisted as enforced by the 60-days law and still, upon analyzes of the variables investigated, identify two groups (age ≤ 50 years and colon tumor) of patients with more possibilities of receiving the first oncologic treatment within 60 days.

CONTRIBUTIONS

José Zago Pulido and Luciana Carrupt Machado Sogame contributed to the study design, acquisition, analysis and/or interpretation of the data, wording and/or critical review. Sabina Bandeira Aleixo contributed to the analysis and/or study design, acquisition, analysis and/or interpretation of the data. All the authors approved the final version to be published.

DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interests to declare.

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