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BRIEF COMMUNICATION

Clinical evidence of neoadjuvant treatment in patients with rectal cancer

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ABSTRACT

Introduction: rectal cancer represents a therapeutic challenge due to its high incidence and surgical complexity; neoadjuvant chemoradiotherapy aims to improve tumor response and reduce recurrences.
Objective: to describe neoadjuvant treatment and its outcomes in patients with rectal cancer treated in Pinar del Río between 2016 and 2021.
Methods: an observational, descriptive, retrospective study conducted in a population of 60 patients with a confirmed diagnosis of rectal cancer treated at the Centro de Atención al Paciente Oncológico III Congreso, who received neoadjuvant therapy during 2016-2021. The documentary review of medical records allowed obtaining information that addressed the variables analyzed, using descriptive statistical methods.
Results: the mean age was 58,0±10,89 years. Moderately differentiated tumors predominated (58,3 %), with lymphovascular invasion in 40,0 % and perineural invasion in 41,7 %, and stages I-II present in 73,3 % of cases. All received chemoradiotherapy (5-fluorouracil 63,3 %; capecitabine 36,7 %; with 50 Gy). A total of 73,3 % underwent surgery before 12 weeks, with abdominoperineal resection predominating (68,3 %). Tumor regression was 66,7 % and nodal regression 61,7 %. According to the Dowrack therapeutic response, 60,0 % reached grade 3 and the adjusted pathological response was 73,3 %.
Conclusions: clinical evidence supports the usefulness of neoadjuvant treatment as a safe and effective strategy in locally advanced rectal cancer, by favoring tumor regression, optimizing surgical conditions, and maintaining a controllable toxicity profile.

Keywords: Rectal Neoplasms; Evidence-Based Practice; Therapeutics; Neoadjuvant Therapy.

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INTRODUCTION

Virtually a good part of all cancers that affect humans arise in the digestive tract. It is said that in the world population, colorectal cancer (CRC) is the third neoplasm in order of frequency and the most frequent malignant process in the European Union. In South America the incidence tends to be medium, and in Africa and Asia it is low. In the United States each year, 300,000 new cases are diagnosed and around 200,000 deaths occur from this cause, while Spain occupies third place in frequency among malignant neoplasms, with an annual incidence of 25,8 % in men, 15,8 % in women and six to ninedeaths per 100,000 inhabitants.[1]

The American Cancer Society recommends one of the following early detection options for both men and women aged 50 years and older: performing a digital rectal examination, annual fecal occult blood testing (FOBT), flexible sigmoidoscopy every five years, annual blood testingoccult in feces plus sigmoidoscopy every five years, double contrast barium enema every five years, colonoscopy every ten years and biopsy.[2] This diagnostic scheme is also applied in Cuba.

In the world, 1.3 cases are detected annually, leaving more than 700 thousand dead. Colorectal cancer is the fourth most common cancer in the region of the Americas. Each year there are more than 240,000 new cases and approximately 112,000 deaths due to this disease in the region. Canada, Uruguay and Barbados have the highest incidence rates while the Central American countries have the lowest. If no action is taken, it is expected that by 2030, the incidence of colorectal cancer will increase by 60 %.[3]

In Cuba, malignant tumors are the second leading cause of death, accounting for 25,350 deaths—a crude rate of 247,5 and an age-adjusted rate of 111,3 (all rates are per 100,000 inhabitants). In 2024, cancer of the rectum, rectosigmoid junction, and anus was the 14th leading cause of cancer-related death in both sexes, with rates of 4,1 for men and 4,5 for women—calculated per 100,000 inhabitants of the respective sex—resulting in a male-to-female (M/F) rate ratio of 0,9. The incidence of this disease among women in Cuba is similar to that observed in the Caribbean and South America; it is higher than in Central America, but lower than the rates reported for the United States and Canada.[4]

The response to neoadjuvant therapy has not been investigated in depth, and this led to the finding of few articles that refer to this in the literature consulted. Ramírez Pantoja et al.,[5] found that the complete or partial response to neoadjuvant treatment justifies its continuation as the therapy of choice, especially in patients whose histological variant is squamous cell carcinoma, so they concluded that the therapyNeoadjuvant therapy shows beneficial effects for patients with anal cancer, especially for those under 60 years of age affected by a well-differentiated carcinoma.

Due to the above, the following research is carried out with the objective of analyzing the clinical evidence of neoadjuvant treatment in patients with rectal cancer treated at the Pinar del Río Hospital between 2016-2021.

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METHODS

An observational, descriptive, retrospective study was carried out, with an exploratory approach, whose design corresponded to a series of cases. The setting was the Cancer Patient Care Center III Congreso, subordinate to the "Abel Santamaría Cuadrado" General Teaching Hospital of the Pinar del Río province. We worked with the population under study, made up of 60 patients with a confirmed diagnosis of rectal cancer who received neoadjuvant treatment in the period 2016-2021, so all available cases in said period were included.

Techniques and procedures for obtaining information

The information collection techniques were based on the review of medical records and institutional records, documentary sources that made it possible to reconstruct the clinical history of each patient. The variables analyzed included sociodemographic characteristics, pathological history, histological and tumor features, therapeutic regimens, clinical response and toxicities. For this purpose, a collection instrument was designed that organized the data into operational categories, facilitating the systematic and uniform recording of the information. The documentary review was carried out meticulously, verifying the consistency of the data and completing the records by cross-consulting the sources available in the institution.

Information processing and analysis

Data analysis was carried out using descriptive statistics, using absolute and relative frequencies for qualitative variables, as well as measures of central tendency and dispersion for quantitative variables. The information collected was organized in a database that allowed the tabulation and systematic processing of the variables, generating frequency distribution tables and numerical summaries that facilitated the interpretation of the results. This procedure made it possible to synthesize the behavior of sociodemographic, histological, therapeutic and tumor response characteristics, as well as identify the main trends of neoadjuvant treatment in the population studied.

Ethical considerations

The Institution's Ethics Committee was consulted to carry out the research, guaranteeing the confidentiality of the information and compliance with the procedures established for the management of clinical data. The principles of the Declaration of Helsinki were respected, ensuring the confidentiality of information and informed consent. The data were used exclusively for scientific purposes, preserving the identity of the patients through identification codes, and the right of the participants to the protection of their personal information was assured, in accordance with national and international regulations. current international agreements on biomedical research.

RESULTS

Age ranged between 30 and 86 years, with a mean of 58,0 years (standard deviation = 10,89); The most represented age group was those over 60 years of age with 73,3 %. Regarding sex, there was a similar behavior in both groups. Of the total number of patients who underwent neoadjuvant treatment, 75,0 % had a pathological history, arterial hypertension was present in 31,7 % and diabetes mellitus in 18,3.

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The data related to the clinical characteristics (Table 1) show that according to the histological differentiation pattern, a predominance of moderately differentiated tumors was found (58,3 %). Lymphovascular and perineural invasion occurred in 40,0 % and 41,7 %, respectively. The presence of N1 lymphadenopathy was observed in 45,0 % of cases. In relation to the pathological stage, the most frequent stages were stage I (58,3 %) followed by IIa (13,3 %). The location of the tumor above seven centimeters from the anal verge was reported in 61,7 % of cases. In relation to tumor size, a predominance of tumors smaller than five centimeters (63,3 %) was recorded.

Table 1. Clinical characteristics of the studied population.

Variable		No.	%
Degree of differentiation	Well differentiated	22	36,6
	Moderately differentiated	35	58,3
	Not very differentiated	3	5
Degree of tumor infiltration	1	8	13,3
	2	28	46,7
	3	8	13,3
	4[a]	9	15
	4[b]	7	11,7
Lymphovascular invasion	Yes	24	40
	No	36	60
Perineural invasion	Yes	25	41,7
	No	35	58,3
Lymph glands	N0	26	43,3
	N1	27	45
	N2	7	11,7
Tumoral size	≤ 5 cm	38	63,3
	> 5 cm	22	36,7
Pathological stage	Stage I–II	44	73,3
	Stage III	16	26,7
Distance from anal verge to tumor	≤ 7 cm	23	38,3
	> 7 cm	37	61,7

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Chemotherapy in combination with radiotherapy was indicated for all patients, the most commonly used cytostatic was 5Fu (63,3 %), the total dose of radiotherapy was 50 Gy, with Cobalt being the most used radiotherapy equipment. 73,3 % of patients were operated on before 12 weeks, with abdominoperineal resection (APR) being the main surgical technique used in 68,3 %. In patients with identified risk factors, 61,7 % underwent adjuvant chemotherapy with the Folfox-4 regimen.

The response to neoadjuvant treatment was adequate, according to the degree of tumor regression, it was observed in 66,7 %, while lymph node regression was required in 61,7 %. The distribution of patients according to the response to neoadjuvant treatment according to Dowrack's classification shows that 60,0 % of patients had an adequate response [category 3], and according to the adjusted pathological response, responder patients predominated. (73,3 %).

Toxicities related to neoadjuvant chemoradiotherapy treatment; indicate how the study recorded a predominance among patients with concurrent neoadjuvant radiotherapy of G1 diarrhea (51,7 %) and G1 proctitis (31,7 %); related to treatment withConcurrent neoadjuvant chemotherapy for diarrhea G1 (58,3 %) presents the most frequent toxicity; which with supportive treatment were not the cause of treatment interruptions.

DISCUSSION

Rectal cancer is a complex disease, with its own natural history and a difficult anatomical location, which makes imaging evaluation not so precise and surgical dissection demanding. These attributes produce understaging, inappropriate neoadjuvant and adjuvant treatments, and surgeries with resection margins that, if they become positive, will reduce the probability of cure and long-term survival with an adequate quality of life. This coincides with the study carried out by Lombana et al.,[6] in Colombia, who report that colon and rectal cancer is the third most common type of cancer in this country. In 2018, 19,258 new cases were diagnosed, of which only 13 % corresponded to stage I, while 40 % were found in stages III or IV. 26 % did not have correct staging.

Incidence and mortality rates show that most cases are diagnosed after the age of 50, among people aged 65-74 years, with an average age of 67. The percentage of death is highest in people between 75 and 84 years old, with an average age of death at 72. About 4 % of colorectal cancers appear in patients under 50 years of age. The most rapid decrease in incidence with respect to the annual rate has appeared in men and women aged 65 years or older, but short-term incidence tends to increase annually for patients under 50 years of age.[7] Results that coincide with this research.

As with many cancers, age is a risk factor for colorectal cancer, especially in those over 50 years of age, since 90 % of all colorectal cancers are diagnosed after this age. Other risk factors include a family history of colorectal cancer, especially if it appears before age 55, doubling the risk of developing it, while a personal history of colorectal cancer or high-risk adenomas (for example, large tubular adenomas larger than 1cm, sessile serrated adenomas or multiple adenomas) indicates an increased future risk of cancer, follow-up of these people after they undergo screening is considered surveillance, not screening. Up to 75 % of people with this neoplasia have a negative family history. Other risk factors are smoking, excessive alcohol intake, poor nutrition, lack of physical activity and obesity.[2,5,7]

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This research, where there were no differences in terms of sex, differs from that carried out by Cayon Poyeaux et al.,[8] where women predominated with 62 cases, for 56,4 %, another study expresses that colorectal cancer is a disease strongly influenced by sex and gender,with mortality rates significantly higher in men than in women. Where sex differences occur along the continuum from diagnosis to survival remains largely unknown. However, they conclude that given that there are minimal sex differences in the data on diagnosis and survival pathways, the higher mortality from colorectal cancer in men seems to be due to exogenous and/or endogenous factors prior to diagnosis that lead to higher incidence rates. elevated. At the same time, they indicate that there are sex and gender differences that suggest that more specific interventions could facilitate prevention and early diagnosis in both men and women.[9]

Neoadjuvant treatment refers to oncologic therapies that are administered before definitive, potentially curative local treatment. The treatment modalities used and their indications vary depending on various factors, such as the location and biology of the tumor, as well as the planned definitive treatment. The influence of these factors is clearly observed in patients with colorectal cancer. Important distinctions can be made between different patient groups, with a more established role for neoadjuvant therapy in patients with rectal cancer than in those with colon cancer.[10,11,12]

However, greater understanding of the heterogeneity of tumor biology and the emergence of new therapeutic options require a more nuanced approach. The challenges are to identify which patients will benefit most from each treatment and, in those with good response, what type of definitive local treatment, if any, is necessary. Neoadjuvant treatments for patients with colon or rectal cancer continue to evolve, increasing the complexity of decision-making for both patients and physicians. This review describes current guidelines and the most recent advances.[13,14,15]

Neoadjuvant radiochemotherapy has been shown to reduce the incidence of local recurrence. Furthermore, it has been shown to increase the probability of preservation of the sphincter apparatus, favoring tumor downstaging and making it possible to achieve a complete pathological response (CPR). CPR has been related to better local control of the disease, greater disease-free survival (DFS) and greater overall survival (OS).[16] Results with which this research agrees.

CONCLUSION

The clinical evidence obtained reaffirms the value of neoadjuvant treatment as a comprehensive strategy in the management of rectal cancer, by demonstrating its ability to promote tumor regression, improve surgical conditions and maintain a controllable toxicity profile. This approach, applied systematically, contributes to optimizing the quality of care and consolidating therapeutic safety in patients with locally advanced disease. The experience accumulated in this period supports the need to continue perfecting protocols, incorporating modern schemes and strengthening clinical follow-up, with the purpose of guaranteeing better prospects for survival and quality of life in the affected population.

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Authors' contribution
YPV: conceptualization, data curation, formal analysis, research, methodology, project administration.
LGBP: conceptualization, data curation, formal analysis, research, methodology, project administration.
AMPM: conceptualization, data curation, formal analysis, research, methodology, project administration.
DALH: conceptualization, data curation, formal analysis, research, methodology, project administration.
RRR: writing the original draft and writing, final review and editing.
MCCM: supervision, validation, visualization, writing the original draft and writing final review and editing.

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