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CHARACTERISTICS OF OUT-OF-POCKET PAYMENT FREQUENCY AMONG COLORECTAL CANCER PATIENTS UNDERGOING CHEMOTHERAPY DEPENDING ON CLINICAL AND ANTHROPOMETRIC INDICATORS

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ABSTRACT

Introduction. Despite improvements in the accessibility of medical services following the introduction of the current healthcare reform in 2017, the issue of out-of-pocket (OOP) payments remains relevant. Colorectal cancer (CRC) is among the three most common malignancies in Ukraine and ranks second in terms of mortality.

Aim. To investigate the frequency of out-of-pocket payments among patients undergoing chemotherapy for colorectal cancer and its association with clinical and anthropometric characteristics.

Materials and methods. In this cross-sectional study, 459 patients who underwent treatment for CRC in Ukraine from July 1, 2023, to June 30, 2024, under the chemotherapy package of the Medical Guarantee Program were surveyed. Patients were divided into two groups according to the presence or absence of OOP payments (121 and 338 patients, respectively). The questionnaire comprised four groups of questions covering general information, attitudes toward informal payments, CRC-related clinical data (including disease stage and TNM classification), chemotherapy-related characteristics, and anthropometric indicators, including weight and height. Comparisons between groups were performed using the chi-square (χ^2) test or Fisher's exact test when the expected frequency in any group was less than 5. The Cochran–Armitage test was used to assess linear trends. Statistical analysis was performed using the R programming language (version 4.3.1) with the EZR graphical user interface (version 1.64).

Results. A statistically significant difference between the OOP payment groups was found for the N component of the TNM classification ($p=0.04$). Statistically significant linear trends were also observed for disease stage and the T and N components of the TNM classification ($\chi^2=4.5$, $p=0.03$ and $\chi^2=6.0$, $p=0.02$, respectively), waiting time for treatment, and the number of completed chemotherapy cycles ($\chi^2=4.3$, $p=0.04$ and $\chi^2=4.9$, $p=0.03$, respectively). Higher values of these variables were associated with a higher frequency of OOP payments. Additionally, OOP payments were more frequent among patients receiving palliative chemotherapy ($p=0.001$), those with metastases ($p<0.001$) or disease progression ($p=0.001$), those with a lower BMI ($p<0.001$), a greater percentage of weight loss over 5 years ($p=0.024$), and a more pronounced decrease in BMI over 5 years ($p<0.001$). No significant differences were found between the patient groups according to the mode of chemotherapy delivery (outpatient vs. inpatient) ($p>0.05$).

Conclusions. The study results indicate that patients at higher risk of OOP payments are characterized by more advanced colorectal cancer and a longer waiting period before initiation of chemotherapy (more than 2 months). OOP payments were more frequently observed among patients with more advanced disease according to the TNM classification, metastases or disease progression, those receiving palliative chemotherapy, and those who had completed a greater number of chemotherapy cycles. Notably, OOP payments were associated with indicators of nutritional depletion, including lower BMI, BMI <18.5 , substantial ($\geq 10\%$) weight loss over 5 years, and a more pronounced decrease in BMI over the same period. Overall, these findings highlight the need to improve the entire cancer care pathway for patients with CRC. To reduce OOP payments among CRC patients receiving chemotherapy at healthcare facilities, measures should include the implementation of an electronic waiting list, increased attention to patients with disease progression, metastases, or nutritional depletion, and regular managerial monitoring of delays in the provision of medical services.

Keywords: body mass index, health care organization and administration, health expenditures, healthcare financing, medical oncology, neoplasm staging, socioeconomic factors.

INTRODUCTION

As part of the ongoing healthcare reform in Ukraine launched in 2017, the National Health Service of Ukraine (NHSU) was established as the single purchaser of healthcare services to implement the Medical Guarantee Program (MGP) [1]. The MGP includes a medical service package for cancer chemotherapy. This package is state-guaranteed, ensuring that treatment is provided free of charge to patients. Furthermore, according to a World Health Organization (WHO) report, access to healthcare services has improved following the implementation of the reform [2]. However, out-of-pocket (OOP) payments continue to pose a significant financial burden for many patients [2, 3].

Colorectal cancer (CRC) is among the three most common malignancies in Ukraine and ranks second in terms of cancer-related mortality, according to data from the National Cancer Registry [4]. In the United States, CRC occupies similar positions in both rankings, according to Siegel et al. [5]. Furthermore, increases in both incidence and mortality have been documented among the economically active population under 65 years of age.

When examining the determinants of OOP payments in cancer care, studies have primarily focused on sociodemographic characteristics (e.g., sex, age, and income level), whereas clinical factors have received comparatively less attention [6-8]. Existing literature indicates that clinical determinants of OOP payments primarily include overall disease stage, TNM classification, metastatic status, and tumor burden [7, 9-12].

According to a study by Tran et al. [13], patients with early-stage disease and those requiring surgery alone demonstrated a greater willingness to incur OOP payments. Conversely, patients with advanced-stage disease and those undergoing chemotherapy were less willing to pay. The authors noted that these findings differ from those of international studies, in which greater disease severity is typically associated with higher patient expenditures [14] and a greater willingness to pay for symptom relief. Tran et al. [13] attributed this phenomenon to the more rapid depletion of household financial resources during advanced stages of disease, along with a stronger belief in a favorable prognosis among patients with early-stage disease.

In a systematic review, Ben-Aharon et al. [15] noted that willingness to incur OOP payments in cancer care is determined not only by objective clinical parameters but also by patients' subjective perception of treatment benefits. Patients typically assess these benefits based on factors such as symptom relief,

improved survival, and quality of life (QoL). Given that patients generally lack specialized medical knowledge, they may rely on readily observable indicators, such as overall well-being and changes in body weight.

The association between body mass index (BMI) and CRC prognosis has been well established. Balakrishnan et al. [16] reported that a low BMI at the initiation of first-line treatment is associated with a poorer prognosis in patients with CRC. Patients with a BMI <18.5 kg/m² had a 50% (95% CI: 43-56) higher risk of death and a 27% (95% CI: 20-34) higher risk of disease progression compared with overweight and obese patients. Notably, the risk decreased with increasing BMI up to 28 kg/m², after which it remained stable. Men with a BMI <18.5 kg/m² had a statistically significantly poorer prognosis than women with a low BMI. Accordingly, patients may perceive weight loss as a potential indicator of poor survival.

Therefore, investigating the association between clinical and anthropometric characteristics of patients with CRC and the frequency of OOP payments is highly relevant for identifying potential measures to prevent or mitigate the adverse effects of financial toxicity.

AIM

To investigate the characteristics of the frequency of out-of-pocket payments among patients undergoing chemotherapy for colorectal cancer with various clinical and anthropometric indicators.

MATERIALS AND METHODS

In cross-sectional study, we surveyed 459 patients undergoing chemotherapy for CRC between July 1, 2023, and June 30, 2024, under the MGP package "Chemotherapeutic Treatment and Care of Patients with Oncological Diseases in Inpatient and Outpatient Settings". The study covers 21 regions of Ukraine and the city of Kyiv. Due to the full-scale invasion by the Russian Federation, respondents from the Donetsk, Luhansk, and Kherson regions, as well as the Autonomous Republic of Crimea, were not surveyed. Patients were divided into two groups based on the occurrence of OOP payments: those who made OOP payments (n=121) and those who did not (n=338). The questionnaire included the clinical and anthropometric parameters of the patients. During the questionnaire design, we accounted for the fact that patients might not know, remember, or accurately report their TNM classification and disease stage due to a lack of medical expertise or immediate access to their medical records. Interviewers asked respondents to consult their medical discharge summaries or

other clinical documents while answering these questions. To improve response quality, two additional questions regarding the presence of metastases and disease progression were included in the survey.

Statistical processing was performed using the R programming language (version 4.3.1) with the EZR graphical interface (version 1.64). Results were presented as absolute frequencies (n) and relative frequencies (%). The normality of the data distribution was evaluated using the Shapiro-Wilk test. For quantitative data with a non-normal distribution, the results are presented as the median and interquartile range (IQR) [Q1, Q3], and comparisons were performed using the Mann-Whitney U test. Comparisons between groups were performed using the chi-square (χ^2) test or Fisher's exact test (if the expected frequency in any group was less than 5). The Cochran-Armitage test was conducted to analyze the presence of a linear trend. The level of statistical significance for all tests was set at $p < 0.05$.

RESULTS

The analysis of the study results is divided into three subcategories: clinical, clinical and organizational, and anthropometric (weight) parameters. First, we present the clinical parameters. Table 1 encompasses the assessment of colorectal cancer severity, evaluated through a simplified three-tier staging system and the TNM classification, which is the international medical

standard for determining the extent of malignancy, along with two supplementary questions.

The distribution of patients between the groups did not differ significantly according to disease stage or overall TNM classification ($p > 0.05$). The only exception was the N category (regional lymph nodes) of the TNM classification, which differed significantly between the groups ($p = 0.04$). Nevertheless, the Cochran-Armitage test revealed statistically significant linear trends for disease stage ($\chi^2 = 4.1$; $p = 0.04$) and for the T and N categories of the TNM classification ($\chi^2 = 4.5$; $p = 0.03$ and $\chi^2 = 6.0$; $p = 0.02$, respectively). The test was not performed for the M category (metastases) because this variable was binary. Thus, as disease severity increased, the proportion of patients reporting OOP payments also increased. OOP payments were less frequent among patients with localized disease (stages 0-II), T0, Tis, and T1 tumors, and N0 or N1 nodal status according to the TNM classification, whereas they were more frequent among patients with more advanced disease.

Patients with metastases and those reporting disease progression incurred OOP payments significantly more frequently ($p < 0.001$ and $p = 0.001$, respectively).

The domain of clinico-organizational parameters is presented in Table 2.

Table 1. Clinical characteristics of patients stratified by out-of-pocket (OOP) payment status

Variable	Category	Out-of-Pocket Payments		p
		NO, n=338	YES, n=121	
		N (%)	N (%)	
Stage	Localized (0-II)	215 (70.3)	70 (61.9)	0.107
	Locally advanced (III)	69 (22.5)	28 (24.8)	
	Disseminated (IV)	22 (7.2)	15 (13.3)	
TNM, T category	T0 or Tis	22 (10.9)	4 (3.9)	0.188
	T1	61 (30.2)	26 (25.5)	
	T2	51 (25.2)	29 (28.4)	
	T3	46 (22.8)	29 (28.4)	
	T4	22 (10.9)	14 (13.7)	
TNM, N category	N0	82 (40.8)	27 (30.0)	0.038
	N1	75 (37.3)	31 (34.4)	
	N2	44 (21.9)	32 (35.6)	
TNM, M category	M0	152 (78.4)	66 (68.8)	0.102
	M1	42 (21.6)	30 (31.2)	
Presence of metastases	No	239 (78.4)	69 (60.5)	< 0.001
	Yes	66 (21.6)	45 (39.5)	
Disease progression	No	268 (85.6)	81 (70.4)	0.001
	Yes	45 (14.4)	34 (29.6)	

Table 2. Organizational characteristics of treatment stratified by out-of-pocket (OOP) payment status

Variable	Category	Out-of-Pocket Payments		p
		NO, n=338	YES, n=121	
		N (%)	N (%)	
Time to treatment initiation, months	≤ 1	231 (69.6)	69 (60.0)	0.114
	1–2	47 (14.2)	18 (15.7)	
	> 2	54 (16.3)	28 (24.3)	
Chemotherapy intent	Curative	238 (77.8)	71 (61.7)	0.001
	Palliative	68 (22.2)	44 (38.3)	
Treatment setting	Outpatient	114 (33.8)	36 (29.8)	0.480
	Inpatient	223 (66.2)	85 (70.2)	
Completed cycles during the study period, N of cycles	≤ 6	270 (80.4)	85 (71.4)	0.087
	7–12	55 (16.4)	26 (21.8)	
	> 12	11 (3.3)	8 (6.7)	

The frequency of OOP payments did not differ statistically significantly based on the treatment setting (outpatient vs. inpatient), time to treatment initiation, or the number of completed cycles during the study period (all $p>0.05$). However, for the latter two parameters, the Cochran-Armitage test revealed a statistically significant linear trend: the frequency of OOP payments increased as the time to treatment initiation and the number of completed cycles increased ($\chi^2=4.3$, $p=0.04$ and $\chi^2=4.9$, $p=0.03$, respectively).

Regarding the number of completed cycles, exceeding 12 cycles generally indicates palliative

chemotherapy, which is prescribed in severe, incurable cases of CRC. Consequently, patients who indicated a palliative intent for their chemotherapy incurred out-of-pocket (OOP) payments statistically significantly more often ($p=0.001$).

Anthropometric parameters included patients' self-reported weight and height at the time of the survey, as well as their weight 5 years prior to the onset of initial CRC symptoms. Based on these data, the body mass index (BMI) and the percentage of weight loss were calculated (Table 3).

The distribution of patients between the groups did not differ significantly according to disease

Table 3. Weight-related anthropometric characteristics of patients stratified by out-of-pocket (OOP) payment status

Variable	Category	Out-of-Pocket Payments		p
		NO, n=338	YES, n=121	
		N (%)	N (%)	
BMI 5 years prior to CRC symptoms	Underweight (< 18.5)	4 (1.2)	0 (0.0)	0.751
	Normal weight (18.5–24.9)	90 (27.9)	34 (31.5)	
	Overweight (25.0–29.9)	158 (48.9)	50 (46.3)	
	Obesity (≥ 30)	71 (22.0)	24 (22.2)	
BMI at the time of survey	Underweight (< 18.5)	10 (3.0)	16 (13.6)	< 0.001
	Normal weight (18.5–24.9)	172 (51.5)	66 (55.9)	
	Overweight (25.0–29.9)	125 (37.4)	28 (23.7)	
	Obesity (≥ 30)	27 (8.1)	8 (6.8)	
5-year weight change, %	Significant weight loss (≥ 10%)	147 (45.8)	67 (61.5)	0.024
	Moderate weight loss (5–9.9%)	79 (24.6)	25 (22.9)	
	Stable weight (< 5%)	62 (19.3)	9 (8.3)	
	Moderate weight gain (5–9.9%)	12 (3.7)	3 (2.8)	
	Significant weight gain (≥ 10%)	21 (6.5)	5 (4.6)	