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# The first report of institutional cancer registry in a center located in Medellín, Colombia

Primer reporte del registro institucional de pacientes con cáncer, en un centro de Medellín, Colombia

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# Abstract

**Purpose:** This is the first report of an institutional-based cancer registry in Clínica de Oncología Astorga, in Medellín, Colombia. It was created to produce local information on socio-demographic and clinical characteristics, therapies, and survival outcomes of patients with the most frequent tumors in the institution. **Methods:** All consecutive patients with cancers of the breast (BC), prostate (PC), lung (LC), colorectal (CRC), ovarian, stomach, pancreas, cervical, and melanoma, diagnosed after January 1/2019, and treated at the institution were included. A description of the entire cohort and of the five most frequent tumor types was performed. Kaplan-Meier curves for each tumor stage were used to estimate overall survival (OS) and progression-free survival (PFS). Statistical analysis was performed using SPSS v22. **Results:** Data from 729 patients were analyzed. The median follow-up was 12.0 months (IQR 5.8-18.1). The main diagnoses were BC, PC, CRC, LC, and cervical cancer in 57.2%, 10.2%, 8.0%, 7.7%, and 5.8% of patients, respectively. The most frequent stage at diagnosis was: stage II for BC (36.6%) and PC (35.1%), stage III for CRC (62.1%) and cervical cancer (50.0%), and stage IV for LC (62.5%). In BC cases, the median PFS for stage IV patients was 10.8 months (95%CI: 8.7-

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Sociedad Colombiana de Hematología y Oncología. Este es un artículo Open Access bajo la licencia CC BY-NC-ND. http://creativecommons.org/ licenses/by-nc-nd/4.0/ 13.0). In LC cases, median PFS and OS for stage IV were 5.6 months (95%CI: 4.1-7.0), and 6.8 months (95%CI: 2.5-11.1), respectively. **Conclusion:** Even though follow-up is short in this first report, PFS for metastatic BC and PFS and OS for metastatic LC reflect the aggressive nature of these conditions in Colombia..

**Keywords:** Population characteristic; malignant neoplasms; neoplasm staging; drug therapy; survival analyses.

#### Resumen

Objetivo: Este es el primer reporte de un registro institucional de cáncer en la Clínica de Oncología Astorga, en Medellín, Colombia. Fue creado para producir información local sobre las características sociodemográficas y clínicas, las terapias y los resultados de supervivencia de los pacientes con los tumores más frecuentes en la institución. Métodos: Se incluyeron todos los pacientes consecutivos con cáncer de mama, próstata, pulmón, colorrectal, ovario, estómago, páncreas, cuello uterino y melanoma, diagnosticados después del 1/enero/2019 y tratados en la institución. Se describió toda la cohorte y los cinco tipos tumorales más frecuentes. Se empleó el método de Kaplan-Meier para estimar la supervivencia global (SG) y libre de progresión (SLP) para cada estadio del tumor. Resultados: Se incluyeron 729 pacientes. La mediana de seguimiento fue 12,0 meses (RIC:5,8-18,1). Los diagnósticos más frecuentes fueron cáncer de mama (57,2%), próstata (10,2%), colorrectal (8,0%), pulmón (7,7%) y cérvix (5,8%). Al diagnóstico, el estadio más frecuente fue: Il para cáncer de mama (36,6%) y próstata (35,1%), III para cáncer colorrectal (62,1%) y cérvix (50,0%) y IV para cáncer de pulmón (62,5%). En cáncer de mama metastásico, la mediana de SLP fue 10,8 meses (IC95%:8,7-13,0). En cáncer de pulmón metastásico, las medianas de SLP y SG fueron 5,6 meses (IC95%:4,1-7,0) y 6,8 meses (IC95%:2,5-11,1), respectivamente. Conclusión: Aunque el seguimiento es corto en este primer informe, la SLP para el cáncer de mama metastásico y la SLP y la SG para el cáncer de pulmón metastásico reflejan la naturaleza agresiva de estas condiciones en Colombia.

**Palabras clave:** Características de la población; neoplasias; estadificación de neoplasias; quimioterapia; análisis de supervivencia.

# Introduction

The growing burden of cancer has multiple social and economic repercussions. The incidence and prevalence of cancer have progressively increased, due to an increase in life expectancy and higher exposure to risk factors implicated in the pathogenesis of the disease <sup>1</sup>. In 2020, 19.3 and 9.96 million new cancer cases and cancer-related deaths occurred, respectively. According to GLOBOCAN 2020, cancer is the second cause of death globally. The main causes of cancer-related deaths include lung, colorectal, hepatocellular, stomach, breast, esophageal, and pancreatic<sup>2</sup>.

GLOBOCAN estimates the incidence and mortality associated with cancer in Colombia using population-based cancer registries obtained from a small number of cities. In 2020, 113,221 new cancer diagnoses and 54,987 cancerrelated deaths were estimated. Breast cancer and prostate cancer were the most common diagnoses in females and males, respectively <sup>2</sup>. There is limited knowledge of cancer demographics and survival outcomes in Colombia. However, attempts to improve registration are increasing. Cancer registries are essential components of cancer control programs, as they provide evidence-based data that can be used to reduce morbidity, and mortality and improve the quality of patient care<sup>3</sup>.

"Clínica de Oncología Astorga" is a tertiary center that provides specialized cancer care in Medellin, Colombia. In 2019, an institutionalbased cancer registry was created to describe socio-demographic and clinical characteristics, therapies, and survival outcomes of patients with the ten most frequent solid tumor types. Here, we present the initial results of this ongoing effort with analyses of breast (BC), prostate (PC), lung (LC), colorectal (CRC), and cervical cancers, as these were the five most frequent solid tumors in the institution.

# Methods

#### Inclusion and Exclusion criteria

Patients with cancers of the breast, prostate, lung, colon, rectum, ovarian, stomach, pancreas, cervix, and melanoma, treated at the Clínica de Oncología Astorga, and diagnosed after January 1, 2019, were included.

To be included, each patient had to approve the collection of his or her personal data and medical information through a *habeas data* format. Patients that declined to participate, those that did not receive a significant portion of their systemic therapy in the institution, and those with only in situ neoplasms, are excluded from the registry (Supplementary Figure).

#### Sampling and Variables

Convenience sampling of patients was performed. Patients evaluated at Clínica de Oncología Astorga who meet eligibility criteria were included. Study variables include sociodemographic information (sex and type of health insurance affiliation), tumor characteristics (ICD-10 diagnosis code, date, and method of diagnosis, TNM staging system, clinical stage, pathology, grade, and biomarkers applicable to each cancer type), treatment information (date of treatment initiation, type, intention and treatment modality) and prognostic variables (vital status, dates of progression/recurrence/ relapse/death and cause of death).

Health insurance affiliation in the Colombian Healthcare system is divided into two mutually exclusive insurance components, the Contributive Regime, and the Subsidized Regime. The Colombian workforce and their families are insured by one of the companies that provide health coverage under the so called Contributive Regime, co-financed by employees and employers. A similar system provides health coverage for the remaining population, under the so called Subsidized Regime, financed through taxes. A small minority of Colombians belong to the so called Special Regimes. These include indigenous people, unionized workers of state companies, the police, and the military forces. Furthermore, individuals can also pay for complementary private health insurance.

#### **Data collection**

Clinical information was gathered on new cancer diagnoses at the institution from January 1, 2019 to June 30, 2021. Retrospective data were acquired from patients diagnosed prior to the start of data acquisition on October 1, 2019.

Afterwards, data was obtained prospectively.

Patient information was obtained from the electronic medical record (software used in the institution) and stored using an electronic spreadsheet. In order to ensure data quality control, data on each patient was validated by at least two of the professionals on the research team.

#### **Data Analysis**

Description of socio-demographic and clinical characteristics of the entire patient cohort, and that of each of the tumors subject to this report was performed. Treatment information and time-to-event outcomes such as disease progression, overall survival (OS), disease-free survival (DFS), and progression-free survival (PFS), whichever applies, for every site were established. Treatments and survival outcomes for each tumor stage and relevant tumor subtypes were also analyzed.

Quantitative variables are described using measures of central tendency and dispersion. Categorical variables are expressed as frequencies and percentages.

Kaplan Meier Curves were used to estimate OS, DFS / PFS. OS was measured from start of treatment to date of death or date of the last patient follow-up. DFS and PFS were measured from the time of initiation of treatment to date of progression or death for patients in earlystage cancer and patients with metastatic disease, respectively. Statistical analysis was performed using SPSS version 22 software.

#### **Ethical considerations**

This study protocol and the habeas data form were approved by Comité de Ética para Investigación Clínica de la Fundación Centro de Investigación Clínica (CEIC), a clinical research ethics committee for the clinic in Medellín. According to Colombian Law 8430 of 1993 the submitted study is classified as risk-free research. Informed consent was not required since the study was a review of medical records, and patients were not subjected to any intervention. Confidentiality was guaranteed by masking the data during the analysis process.

#### Results

#### Entire cohort

Data from 729 patients who met eligibility criteria prior to cut-off date were analyzed (Supplementary Figure). The median followup was 12.0 months (IQR 5.8-18.1). The median age was 63 years (IQR 53.2-73.6), and 76.7% of patients were female. Concerning affiliation to the Colombian Healthcare system, 68.2% of patients belonged to the Contributive Regime. Main diagnosis in the whole cohort were BC, followed by PC and LC, in 57.2%, 10.2% and 7.7%, respectively (Table 1). In women, BC, cervical cancer, CRC, ovarian cancer and LC accounted for 73.9%, 7.5%, 6.3%, 4.7%, and 4.5%, respectively. In men, PC, LC, CRC, gastric cancer and pancreatic cancer were the five most frequent diagnosis, each representing 43.5%, 18.2%, 13.5%, 9.4% and 7.6%, respectively. At the time of analysis, 84.2% of the patients were alive (Table 1).

 Table 1. Demographic and clinical characteristics of the entire cohort.

	_							
Characteristics	Frequency N=729	Percentage						
Age at diagnosis	63.0 years	(53.2 -73.6)						
(Me- IQR)* Sex								
		76 7						
Women Site of re	559	76.7						
Medellín	405	55.6						
Metropolitan Area	405	25.5						
Other		23.5 18.9						
Healthcare Syste	138 m Affiliation*							
	497							
Contributive Regime	-	68.2						
Subsidized Regime	29	4.0						
Private Health Insurance	193	26.5						
Special Regime	9	1.2						
Particular	1	0.1						
Cancer d	-							
Breast	417	57.2						
Prostate	74	10.2						
Lung	56	7.7						
Colon	37	5.1						
Rectum	21	2.9						
Cervical	42	5.8						
Ovarian	26	3.6						
Stomach	22	3.0						
Pancreatic	22	3.0						
Melanoma	12	1.6						
Stage at c	-							
	158	21.7						
11	209	28.7						
	215	29.5						
IV	142	19.5						
Unknown	5	0.6						
ECC								
0	368	50.5						
1	275	37.7						
2	36	4.9						
3	6	0.8						
4	2	0.3						
Unknown	42	5.8						
Vital Status								
Alive	614 15	84.2 2.1						
Lost to follow-up								
Dead	100	13.7						
Related to the	65	65.0						
disease								
Not related to the disease	11	11.0						
Unknown	24	24.0						

**Nota:** \* Me (IQR): Median- Interquartile Range. \*\*Affiliation type to the healthcare system. ECOG: Eastern Cooperative Oncology Group Performance Status

#### **Breast Cancer**

**Demographic and clinical characteristics:** In this group of patients (N=417), 99.0% were female and median age at diagnosis was 61 years (IQR 50.4-70.5). The median follow-up for this group was 13.0 months (IQR 3.5-18.6). Invasive ductal carcinoma was the histology diagnosis in 84.6%. Estrogen-receptor, and progesterone-receptor were positive in 76.7%, and 64.3% of the patients, respectively. Her-2 was positive in 19.7%, and 13.7% were triple-negative. Stage I or II at diagnosis was established in 69.0%. At the time of analysis, 93.5% of the patients were alive (Table 2).

 Table 2. Demographic and clinical characteristics of five solid tumor types.

Characteristics		Breast		Prostate		Diagnosis Colorectal Cancer		Lung		Cervical	
		Cancer		Cano	Cancer*		=58	Cancer		Cancer	
		n=4	n=417		n=74			n=56		n=42	
	Age at diagnosis	61 ye	ears	73.7 years		70.1 years		69.3 years		44.4 years	
	(Me- IQR)*	(50.4 - 70.5)		(67.5 - 79.6)		(57.9- 76.5)		(62.1 - 77.0)		(35.9 - 59.4)	
Demographic	Sex n-%										
	Women	413	99.0	N/A	N/A	35	60.3	25	44. 6	42	100
	Men	4	1.0	74	100	23	39.7	31	55. 4	N/A	N/A
	Well	46	11.0	11	14. 9	23	39.7	4	7.1	10	23.8
Grade of Differentiation <sup>*</sup>	Moderately	255	61.2	22	29. 7	28	48.3	26	46. 4	23	54.8
n-%	Poorly	110	26.4	39	52. 7	6	10.3	12	21. 4	2	4.8
	Unknown	6	1.4	2	2.7	1	1.7	14	25. 0	7	16.7
	I	135	32.4	7	9.5	0	0	0	0	11	26.2
Stage at	Ш	153	36.6	26	35. 1	9	15.5	3	5.4	6	14.3
diagnosis n-%	III	100	24.0	16	21. 6	36	62.1	18	32. 1	21	50.0
	IV	29	7.0	25	33. 8	12	20.7	35	62. 5	3	7.1
	No information	0	0	0	0	1	1.7	0	0	1	2.4
	Alive	390	93.5	66	89. 2	47	81.0	25	44. 6	38	90.4
	Lost to follow-up	3	0.7	5	6.7	1	1.7	1	1.8	2	4.8
	Dead	24	5.8	3	4.1	10	17.2	30	53. 6	2	4.8
Vital Status n-%	Related to the disease	18	75.0	2	66. 7	5	50.0	19	63. 3	2	100
	Not related to the disease	1	4.2	0	0	4	40.0	6	20. 0	0	0
	No information	5	20.8	1	33. 3	1	10.0	5	16. 7	0	0

**Nota:** \*Me (IQR): \*Median- Interquartile Range. \*\*Grade of differentiation of Prostate Cancer according to Gleason's groups: Well differentiated =Group 1, moderately differentiated=Groups 2 and 3, and poorly differentiated=Groups 4 and 5.

#### **Treatment description:**

BC patients were classified into subgroups by histopathology into luminal, Her-2-positive, and triple negative (TNBC).

In Luminal BC, Endocrine Therapy (ET) was the first systemic therapy in 43.5% of patients. In stage I, 81.7% were treated with adjuvant ET without adjuvant cytotoxic chemotherapy. Genomic test with the 21-gene recurrence score was performed in 31 (28.4%) stage I patients. Adjuvant chemotherapy was administered in 5 (16.1%) patients with genomic high risk. Only 1 out of 26 patients with low genomic underwent adjuvant chemotherapy (test result arrived too late to inform therapy).

ET was the initial systemic therapy in 21.2%, 12.7%, and 26.7% of patients with stage II, III, and IV, respectively (Table 3).

 Table 3. Initial treatment description according to clinical stage of five solid tumor types.

Initial treatment according to	Clinical Stage							
diagnosis	I			П	- 111		IV	
Luminal Breast Cancer (n=278)	n=109		n=99		n=55		n=15	
Hormonal therapy	89	81.7	21	21.2	7	12.7	4	26.7
Chemotherapy	20	18.3	77	77.8	48	87.3	8	53.3
CDK4/6 inhibitors	0	0	0	0	0	0	3	20.0
Definitive surgery*	0	0	1	1.0	0	0	0	0
Her-2 positive Breast Cancer (n=82)	n=18		n=29		n=23		n=12	
Hormonal therapy	1	5.6	0	0	0	0	0	0
Chemotherapy	0	0	1	3.4	0	0	2	16.7
Anti-Her2 therapy	17	94.4	28	96.6	23	100	9	75.0
CDK4/6 inhibitors	0	0	0	0	0	0	1	8.3
Triple -negative Breast Cancer (n=57)	n=8		n=25		n=22		n=2	
Chemotherapy	8	100	24	96.0	22	100	2	100
Definitive surgery*	0	0	1	4.0	0	0	0	0
Prostate Cancer (n=74)	n=7		n=26		n=16		n=25	
Antiandrogen therapy	0	0	0	0	0	0	9	36.0
ADT <sup>†</sup>	0	0	1	3.8	0	0	2	8.0
Chemotherapy	0	0	0	0	0	0	11	44.0
Radiotherapy + ADT	3	42.9	24	92.3	16	100	3†	12.0
Radiotherapy	4	57.1	1	3.8	0	0	0	0
Colon Cancer (n=37)		n=0	n=5		n= 24		n=8	
Chemotherapy	0	0	5	100	23	95.8	3	37.5
Chemotherapy + monoclonal antibody	0	0	0	0	1	4.2	5	62.5
Rectum Cancer (n=20)	n=0		n=4		n=12			n=4
Chemotherapy	0	0	1	25.0	2	16.7	0	0
Chemoradiotherapy	0	0	3	75.0	9	75.0	2	50.0
Chemotherapy + monoclonal antibody	0	0	0	0	1	8.3	2	50.0
Lung Cancer (n=56)	n=0		n=3		n=18		n=35	

Chemotherapy	0	0	2	66.7	4	22.2	14	40.0
Chemoradiotherapy	0	0	1	33.3	8	44.4	1	2.9
Immunotherapy	0	0	0	0	0	0	2	5.7
Chemotherapy + Immunotherapy	0	0	0	0	5	27.8	9	25.7
Chemotherapy + anti-angiogenic therapy	0	0	0	0	1	5.6	4	11.4
ткі₅	0	0	0	0	0	0	4	11.4
Clinical trial	0	0	0	0	0	0	1	2.9
Cervical Cancer (n=41)	n=11		n=6		n=21		n=3	
Definitive surgery*	7	63.6	0	0	0	0	0	0
Chemoradiotherapy	3 <sup>‡</sup>	27.3	6	100	19	90.5	2	66.7
Chemotherapy	1 <sup>§</sup>	9.1	0	0	0	0	0	0
Clinical trial	0	0	0	0	2	9.5	1"	33.3

**Nota:** \*Surgical treatment alone. ADT: Androgen Deprivation Therapy. †These 3 patients belong to stage IVA. TKI: Tyrosine kinase inhibitors. ‡Two patients were not candidates for surgery, and one patient required adjuvant chemoradiotherapy. §This patient received neoadjuvant chemotherapy in the setting of fertility preservation. This patient was classified as stage IVA.

In the 82 Her-2-positive patients, 93.9% received anti-Her-2 therapy. Five patients did not receive it. One patient refused, and in four anti Her-2 therapy was not administered due to lack of insurance coverage.

Chemotherapy was administered in 98.2% of the 57 patients with TNBC. One patient refused, and underwent surgery.

**Outcomes:** At the time of analysis, disease progression was observed in 3 patients (2.2%) in stage I, 8 (5.2%) in stage II, 12 (12.0%) in stage III, and 17 (58.6%) in stage IV. Median DFS was not reached in stages I through III. Median PFS for stage IV was 10.8 months (95%CI: 8.7-13.0) (Figure 1A). One-year survival was 98.2%, 96.2%, 88.2% and 71.8%, for stages I, II, III and IV, respectively. Twenty-four (5.8%) patients died during follow-up. Of these, 18 (75.0%) were deemed disease-related (Table 2). Median OS according to stage was not reached at the time of analysis (Figure 1B).

#### **Prostate Cancer**

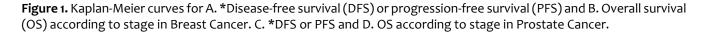
Demographic and clinical characteristics:

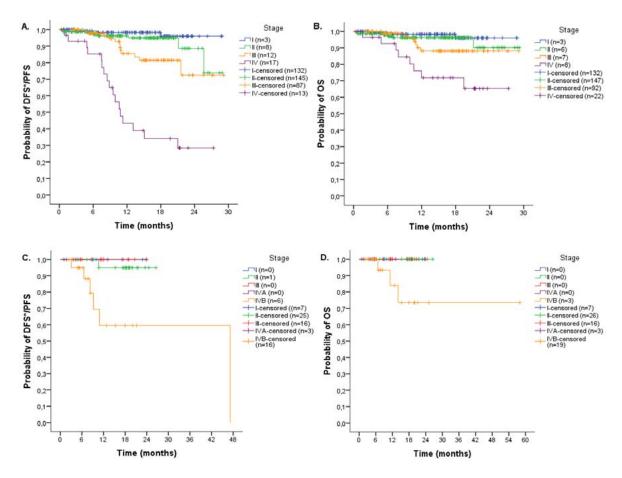
Seventy-four men were included. Median age was 73.7 years (IQR 67.5-79.6). Median followup was 12.4 months (IQR 6.2-19.1). Thirty-nine patients (52.7%) had poorly differentiated histology (Gleason Grade Group 4 to 5). Stage II and stage IV were assigned in 35.1% and 33.8% of cases, respectively. Metastatic stage IV (IVB) accounted for 88% of stage IV (22 patients). At the time of analysis, 66 (89.2%) patients were alive (Table 2).

**Treatment description:** For stage I disease, radiotherapy, or radiotherapy plus Androgen Deprivation Therapy (ADT) were used in 42.9%, and 57.1%, respectively. Radiotherapy plus ADT was the initial treatment in 92.3%, 100% and 100% in stage II, stage III and stage IVA (Table 3). In stage IVB, 11 (50.0%) patients received chemotherapy (plus either ADT or orchiectomy), 7 (31.8%) underwent orchiectomy plus antiandrogen therapy, 1 (4.5%) received ADT plus antiandrogen therapy, 1 (4.5%) was treated with radiotherapy plus antiandrogen therapy plus antiandrogen therapy plus antiandrogen therapy plus antiandrogen therapy plus ADT, and 2 (9.1%) were treated with ADT, as their initial systemic therapy.

Outcomes: At the time of analysis,

progression was observed in 1 (3.8%), and in 6 (27.3%) patients in stage II and IVB, respectively. Three (4.1%) patients, with stage IVB died during follow-up. Of these, 2 (66.7%) were deemed disease-related (Table 2). One-year survival was 100% for stages I, II, III and IVA, and 84.0% for stage IVB. Medians of DFS, PFS and OS were not reached for any clinical stage (Figure 1C and 1D).





#### **Colorectal Cancer**

**Demographic and clinical characteristics:** A total of 58 patients were included. Women accounted for 60.3%. Median age was 70.1 years (IQR 57.9-76.5) (Table 2). Stage III in 36 (62.1%) patients. Colon and rectal sites accounted for 37 (63.8%), and 21 (36.2%), respectively. For colon cancer, 22 (59.5%) were located in the right-side. Median follow-up was 14.0 months (IQR 7.7-17.9) and 15.5 months (IQR 6.3-17.7), for colon and rectum, respectively. At the time of

analysis, 81.0% of the patients were alive (Table 2).

**Biomarkers:** Nine out of 12 (75%) patients with stage IV CRC were tested for RAS mutations and 2 (16.7%) patients were also tested for BRAF mutations. RAS and BRAF mutations were found in 8 (88.8%) and 1 (50.0%) patients, respectively. Microsatellite instability (MSI) test was performed in 2 (22.2%) stage II patients, 3 (8.3%) in stage III, and 3 (25.0%) patients in stage IV. Microsatellite instability was found in none. **Treatment description:** All stage II and 95.8% stage III colon cancer patients were treated with adjuvant chemotherapy. For rectal cancer, chemo-radiotherapy was the initial treatment in 75.0% in both, stage II and in stage III disease.

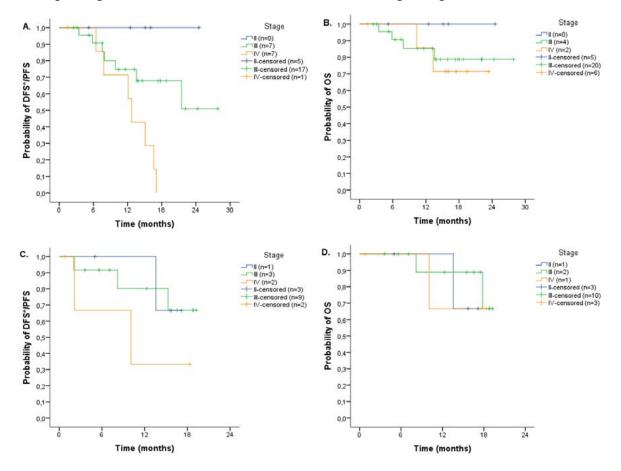
In stage IV colon cancer, 1 patient was treated with chemotherapy; 2 patients underwent surgery with curative intent, followed by adjuvant chemotherapy; and five patients underwent chemotherapy plus a biologic agent. Two out of 4 stage IV rectal cancer patients received chemotherapy plus a biologic agent as first line systemic therapy. Chemo-radiation was administered to the other 2 (Table 3).

**Outcomes:** Disease progression was observed in 7 stage III (29.2%), and in 7 stage IV

(87.5%) colon cancer patients, respectively. Six patients (16.2%) patients died during follow-up. In 2 (33.3%) patients' death was deemed disease-related. One-year survival was 100%, 85.3%, and 85.7% for stage II, III and IV, respectively. The median DFS, PFS and the median OS were not reached (Figure 2A and 2B).

For rectal cancer, disease progression was observed in 1 (25.0%), 3 (25.0%), and 2 (50.0%) stage II, stage III and stage IV, respectively. At the time of analysis, 4 (19.0%) patients had died. Of these, 3 (75.0%) were disease-related. One-year survival was 100%, 88.9%, and 66.7% for stage II, III and IV, respectively. The median PFS and the median OS were not reached (Figure 2C and 2D).

**Figure 2.** Kaplan-Meier curves for A. \*Disease-free survival (DFS) or progression-free-survival (PFS) and B. Overall survival (OS) according to stage in Colon Cancer. C. \*DFS or PFS and D. OS according to stage in Rectum Cancer.



#### Lung Cancer

**Demographic and clinical characteristics:** Fifty-six patients were included. Men accounted for 55.4%. Median age at diagnosis was 69.3 years (IQR 62.1-77.0) (Table 2). Median followup was 7.0 months (IQR 2.4-16.6). The types of histology observed were adenocarcinoma in 30 (53.6%) patients, squamous cell carcinoma in 21 (37.5%), small-cell carcinoma in 3 (5.4%), and adenosquamous carcinoma 2 (3.6%) patients. Stage IV was established in 62.5%.

**Biomarkers:** PD-L1 expression was performed in 36 (64.3%) patients and EGFR mutation and ALK rearrangements were tested in 27 (48.2%). For non-squamous tumors a positive PD-L1 expression was observed in 10/24 (41.7%) patients, ALK-positive in 3/23 (13%), and EGFR mutation in 3/23 (13.0%). In squamous histology, positive PD-L1 expression and ALK-rearrangements were found in 9 out of 12 (75.0%) patients, and in 1 out of 4 (25.0%) patients, respectively. No EGFR mutation was observed.

**Treatment description:** Adjuvant chemotherapy was the first systemic therapy in 2 out of 3 stage II patients. In stage III, 44.4% (8 out of 18) underwent chemoradiotherapy. Of the 35 patients with stage IV, 18 (51.4%) received chemotherapy, 11 (31.4%) underwent immunotherapy with or without chemotherapy, and 6 (17.1%) received other treatment modalities (Table 3).

**Outcomes:** At the time of analysis, progression was observed in 2 (66.7%), 9 (50.0%), and 24 (68.6%) patients with stage II, III, and IV, respectively. In NSCLC patients, median DFS was 7.2 months (95%CI: 6.3-8.1), and not reached, for stage II and III, respectively; and median PFS was 5.6 months (95%CI: 4.1-7.0) for stage IV patients. (Figure 3A).

At the time of analysis, 25 (44.6%) patients

were alive (Table 2). One-year survival was 66.7%, 57.7%, and 32.9%, for stages II, III and IV, respectively. Thirty (53.6%) patients died during the study period. Of note, 63.3% of the deaths were disease related (Table 2). In NSCLC, median OS for patients with stage IV was 6.4 months (95%CI: 3.4-9.4). For the remaining stages, median OS was not reached (Figure 3B).

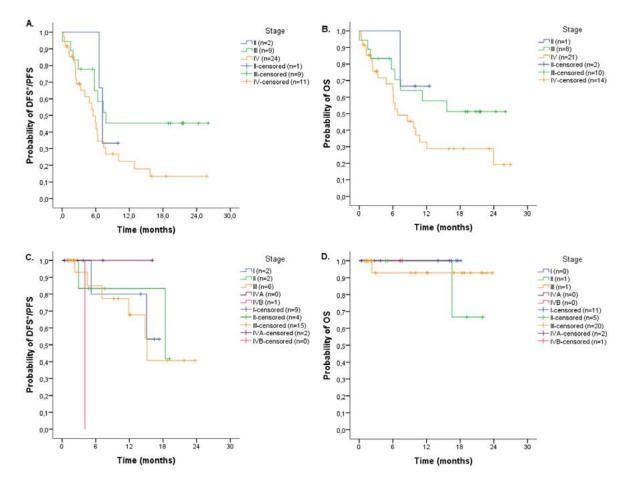
#### **Cervical Cancer**

**Demographic and clinical characteristics:** Forty-two women were diagnosed with cervical cancer. The median age at diagnosis was 44.4 years (IQR: 35.9-59.4) (Table 2). The median follow-up was 9.6 months (2.1-17.7). According to histology, 85.7% and 14.3% were squamous cell carcinoma and adenocarcinoma, respectively. At diagnosis, 50.0% of the patients were stage III (Table 2). Two and 1 stage IV patients were classified as IVA and IVB, respectively.

**Treatment description:** Definitive surgery was performed in 7 out 11 (63.6%) stage I patients. Chemoradiotherapy with curative intent was delivered to all 6 (100%) and 19 out of 21 (90.5%) stage II and stage III patients (Table 3). For stage IVA patients, treatment consisted of either chemoradiotherapy (50.0%) or enrollment in a clinical trial (50.0%). The patient classified as stage IVB received palliative chemoradiotherapy.

**Outcomes:** At the time of analysis, progression occurred in 2 (18.2%), 2 (3.3%) 6 (28.6%), 1 (100%) stages I, II, III and IVB patients, respectively. Disease progression was not observed in stage IVA patients.

At the time of analysis, 90.4% of patients were alive (Table 2). Six-months survival was 100% for stages I, II, IVA, and IVB, and 92.9% for stage III. Two (4.8%) patients died during followup. Deaths were due to progression (Table 2). Medians DFS, PFS and OS were not reached (Figure 3C and 3D). **Figure 3.** Kaplan-Meier curves for A. \*Disease-free survival (DFS) or progression-free survival (PFS) and B. Overall survival (OS) according to stage in Lung Cancer. C. \*DFS or PFS and D. OS according to stage in Cervical Cancer.



#### Discussion

This is the first report of an institutionalbased tumor registry in Clínica de Oncología Astorga, in Medellín, Colombia. The five most frequent cancers are reported, including: breast, prostate, lung, colorectal and cervical cancers. Basic demographic data, stage distribution and survival outcomes are reported to the extent of their availability. Women account for 76.7% in this study, a higher percentage than those reported by population-based registries in the Colombian cities of Cali, Bucaramanga and Pasto with women accounting with 54.7%, 57.2% and 57.2%, respectively <sup>4-6</sup>. A strong emphasis in BC treatment in the Clínica de Oncología Astorga may explain this disparity.

According Colombian to government sources, the contributive regime account for health coverage in 48.0% of the population, and subsidized regime accounts for 47.0% <sup>7</sup>. In our registry 94.8% are enrolled in the contributive regime (these include 26.6% with treatment covered at least in part be a supplementary private insurance). The subsidized regime accounts for only 4.0% of the registry population, as a result of locating the main offices for the institutions only in big cities, and due to the different contracts with insurance companies. The subsidized regime in Colombia insures the most vulnerable in the social-economic ladder, and health disparities in this population have been previously described <sup>8</sup>. The present study results cannot be generalized to this population.

Between 2008 and 2012, 12613, and 5021 new cancer diagnoses were reported in the population-based cancer registry in Cali, and Bucaramanga, Colombia, respectively <sup>4,5</sup>. In these cities, the five most frequent cancer sites reported in women were BC, cervix, colorectal, thyroid, and stomach cancer. In men the five most frequent cancer sites reported were PC, stomach, colorectal, LC and lymphomas. The five most frequent cancer sites in our study are the same as those reported in Cali and Bucaramanga, except for a higher frequency of ovarian cancer and LC in women and of pancreatic cancer in men.

Breast cancer in young women is more frequent in Latin America than in the US, with 20% and 12% of new cases diagnosed at age <44, respectively 9. We found 13.2% of BC were diagnosed at <44 years, somewhat less than expected considering that Colombia is a Latin American country. In our registry, 8.2% of BC patients were <40 years old at diagnosis, a figure similar to the 9.6% reported by Instituto de Cancerología – Clínica Las Américas AUNA, a specialized cancer institute for the aforementioned clinic in Medellín<sup>10</sup>. The totality of the current study data from young women at our institution diagnosed with BC is not consistent with the available information regarding the majority of BC diagnosis.

In a hospital-based registry from Instituto Nacional de Cancerología in Bogotá, Colombia, 1.928 women with BC diagnosed in 2007, 2010, and 2012 were reported. Clinical stage distribution was 5.8%, 28.3%, 39.0%, 7.3%, and 19.7% for stages I, II, III, IV, and not recorded, respectively <sup>11</sup>. In the present registry, we found 413 women with BC. At diagnosis, 32.2%, 37.0%, 23.5%, and 7.3% were classified as stages I, II, III, and IV, respectively. The majority of BC patients at our institution are diagnosed in early stages, consistent with better access to health resources by our patient population. As for prostate cancer, a cross-sectional analysis of 2.617 men with prostate cancer in Colombia was reported in 2018 <sup>12</sup>. Median age was 68 years (IQR 62–74), 49.2% presented in I-II. Patients received systemic therapy, radiotherapy or surgery as their main treatment modality in 35.4%, 22.2%, and 28.7%, respectively. In this study the median age was 73.7 (IQR 67.5-79.6%), with a 55.4% presenting in stages III-IV. The latter result can be explained by the absence of urologist at our institution since early stage disease is treated by this specialty.

Between 2011 and 2015, a retrospective cohort study included 1.500 patients with CRC treated at an oncology center in Medellín, Colombia. Stage distribution was 10.9%, 23.7%, 33.5%, 22.1% and 8.7% for stages I, II, III, IV, and not recorded respectively <sup>13</sup>. Stage III disease was dominant at our institution accounting for 62.1%. This can also be explained by the lack of surgical oncology service at our institution at that time. A concentration of patients likely to benefit from systemic therapy might explain why 82.8% of patients in the registry presented in stage III/IV.

The Colombian government registered 1.414 new lung cancer cases in 2020 14. Median age was 68 (IQR: 60 – 75) and 54.4% were men. Stage distribution was: 1.1%, 6.4%, 5.9%, 12.7%, 54.7% and 19.2% for stages 0, I, II, III, IV and not recorded, respectively. Both age and stage distribution in our data set yield similar results with median age of 69 (IQR: 62.1-77%), and with 62.5% presenting in stage IV disease. In our study median PFS and OS in stage IV NSCLC patients was 5.6 months and 6.4 months, respectively. Survival outcomes in LC have not been previously reported in Colombia in institutionalbased cohort for this condition. Therefore, this is a contribution of this study to the knowledge of the field in Colombia.

In Cervical cancer, a population-based cohort study was reported including 220 women

in Manizales, Colombia, between 2003 and 2007. Stage distribution was 7.3%, 16.4%, 13.6%, 5.9%, and 56.8% for stages I, II, III, IV, and not recorded, respectively <sup>15</sup>. In our study 97.6% patients were staged and 50.0% were stage III, probably reflecting a bias of referral of patients likely to require combined modality therapy.

To our knowledge this is the first multitumor report of an institutional-based registry in Colombia. The strengths of oncology for the study are based on the reliability of the information the result of its prospective collection. Demographic data, stage, key clinical elements, and survival outcomes, reported in this study reflect their true nature. The percentage of unknown / non-available critical results are almost none in our registry. Of note, survival curves are very reliable and are likely to yield more information in future reports. But lung cancer and metastatic breast cancer survival curves begin to reflect the poor outcomes usually associated with these conditions. Another strength of the study is the accurate description of the main treatment modalities in use, a feature not available in most cancer registries.

There are several limitations for this registry: First, there is a short follow-up period as this is a work in progress. Second, there appears to be a potentially biased stage distribution in some of the tumors reported. As a result of the lack of some surgical field specialists at the time of data collection. This may explain some atypical stage distributions in some tumor types within the registry, and the current findings may not reflect the true stage distribution in Colombia as a whole. However, the latter was not an issue for breast cancer, since breast cancer surgeons were active at the institution since the beginning of the study.

# Conclusion

Even though follow-up is short in this first

report of a prospective institutional-based cancer registry, PFS for metastatic BC and PFS and OS for metastatic LC reflect the aggressive nature of these conditions in Colombia. The surprisingly short median survival in advanced LC found in this real-world evidence is unexplained. In the future, further data analyses will also provide unique information not previously reported elsewhere about these and other cancer outcomes in Colombia.

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#### **Conflict of Interest**

The authors declare that they have no conflicts of interest.

#### Contributions

Beatriz E. Preciado: Conception/ Conceptualization/ Collection and data/ Validation data Writing - Original Draft/ Writing -Review & Editing.

Diego Morán: Creation of the data collection tool/Provision of study patients/ Validation data/ Writing - Review & Editing.

Camila Lema: Collection and validation data/ Formal analysis/ Writing - Original Draft/ Writing - Review & Editing.

María J. Fernández: Collection and validation data / Writing - Original Draft.

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Mauricio Luján: Provision of study patients/ Validation data/ Writing - Review & Editing.

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#### **Supplementary Figure**

Patient flow chart

