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Regional Registries in Latin America COLOMBIAN EXPERIENCE

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Asociación Colombiana de Hematología y Oncología

March 29 2021

Disclosures for Virginia Abello, MD

In compliance with ACCME policy, ASH requires disclosures to the session audience:

- **Research Funding:** AbbVie; Amgen; Astellas; Dr. Reddy's; Takeda
- **Honoraria:** AbbVie; Amgen; Astellas; Dr. Reddy's; Janssen; Novartis; Sanofi; Takeda

Discussion of off-label drug use: Not applicable



Regional Registries in Latin America

Colombian RENEHOC Registry



RENEHOC
Registro de Enfermedades
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- According to the National Administrative Department of Statistics (DANE), population : **50'372.424** inhabitants.
- The country is divided into 33 departments.
- 77.1% of people live in urban areas.
- Universal health insurance coverage:
- ✓ **Subsidized health insurance** regimen represent people with unstable or informal work, or unemployed people who need subsidy from the government to get access to health services.
- ✓ **Contributory health regimen:** Represents people with stable work who contribute with part of their salary to the health system.



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- From January 2018-January 2019 **29151** new cases of cancer were diagnosed.
- According to **Cuenta de Alto Costo** there were **2244** prevalent cases of CML in 2019.
- **SISPRO** reports 5920 medical consults between 2019-2020 for CML.
- **Globocan** reports **9661** prevalent cases for all leukemias. No specific information provided on CML.
- **DANE** reports 1329 deads in Colombia due to CML from 2005-2013.

**THERE IS NO INFORMATION ON SPECIFIC NATIONAL
OUTCOMES FOR CML**

Situación del cáncer en Colombia 2019- Cuenta de Alto Costo
GLOBOCAN 2020

<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/relevancia-imatinib-impacto-salud-publica.pdf>



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2014: First
idea registry
on CMPN

2017: First
RENEHOC
investigators
meeting

2018: MM
recruitment
started

2019: CML
recruitment
started

2020: AML-PETHEMA
recruitment started

2021:

- 1774 patients included in RENEHOC
- 28 investigators
- 17 centers



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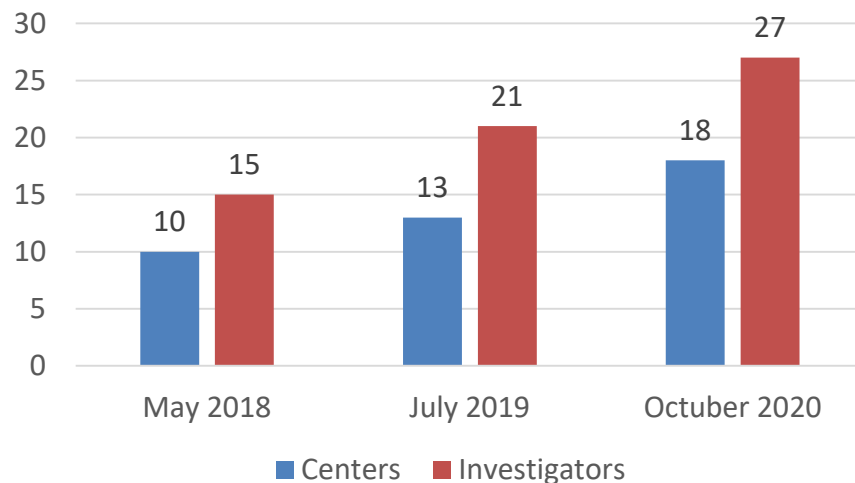
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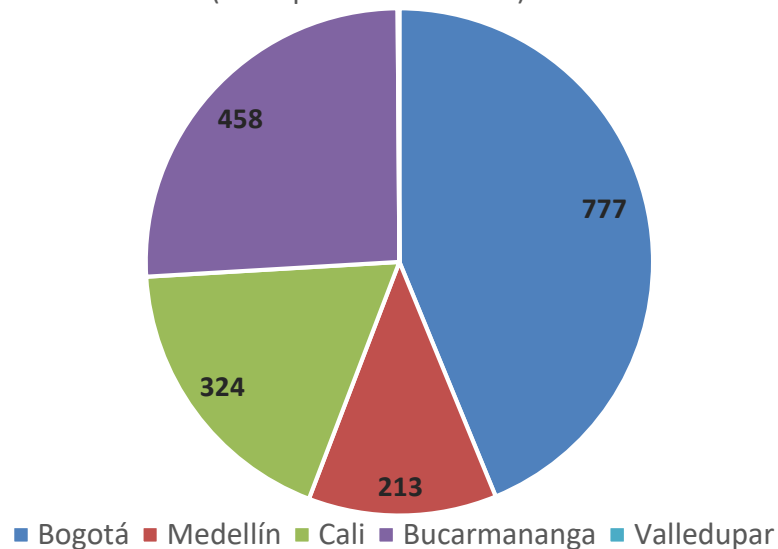


RENEHOC INVESTIGATORS AND CENTERS



CENTERS DISTRIBUTION

(1774 patients included)



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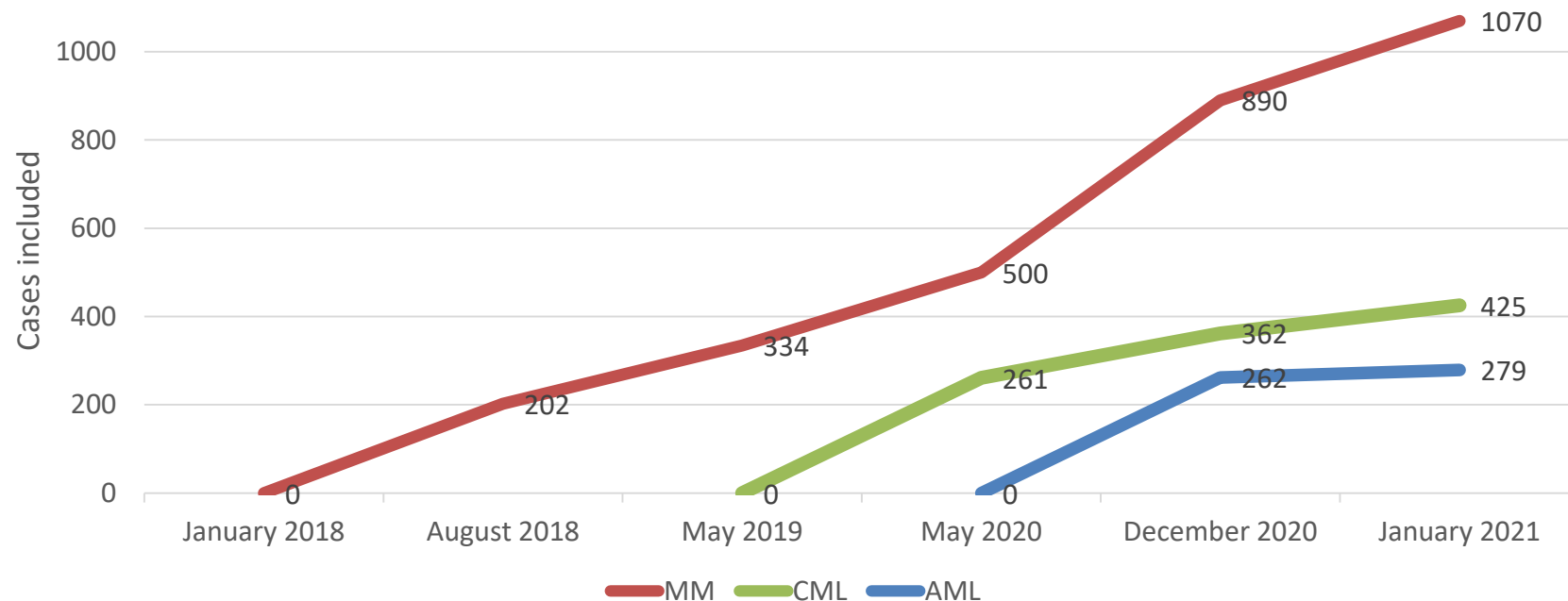
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RENEHOC REGISTRY RECRUITMENT GROWTH

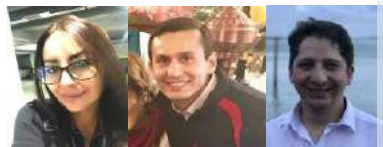


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María Helena Solano



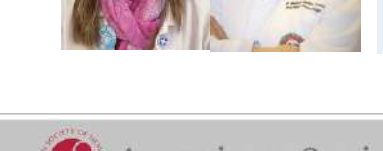
Claudia Sossa



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William Mantilla

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Juan Manuel Herrera

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Jair Figueroa

Luis Salazar

Daniel Espinosa

Claudia Casas

Carmen Rosales

Lina Abenosa

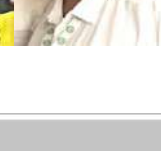
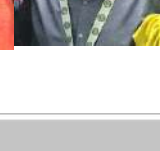
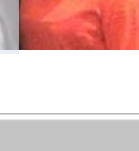
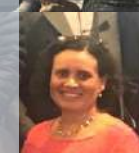
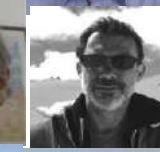
Guillermo Quintero

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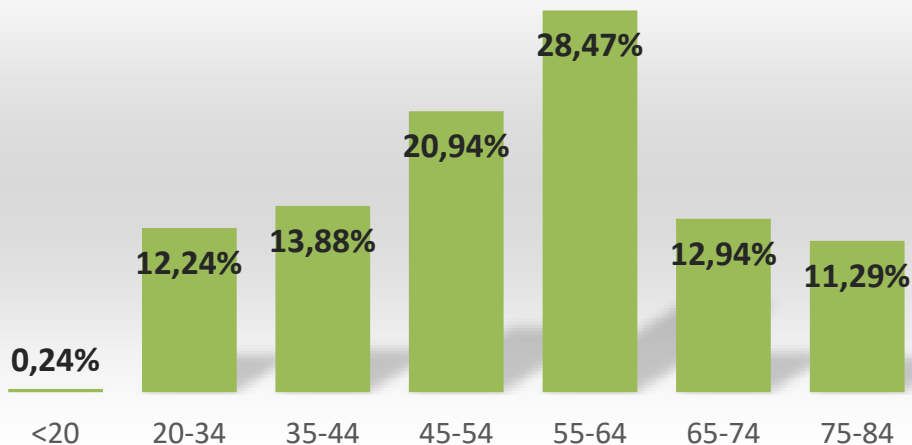
PATIENT CHARACTERISTICS

N= 425

Age at diagnosis yrs. (mean, SD)

54 (15.19)

Percent of new cases by age group



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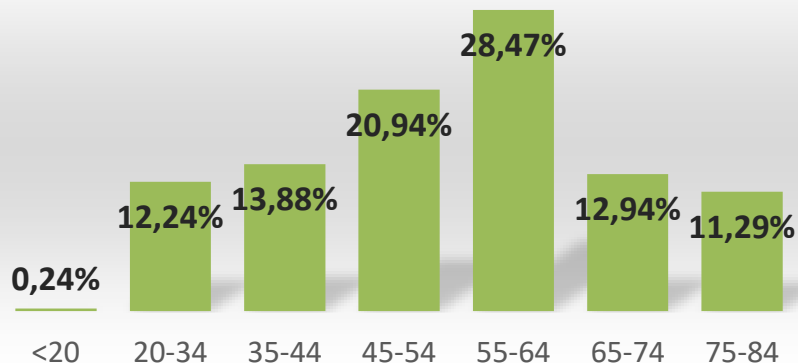
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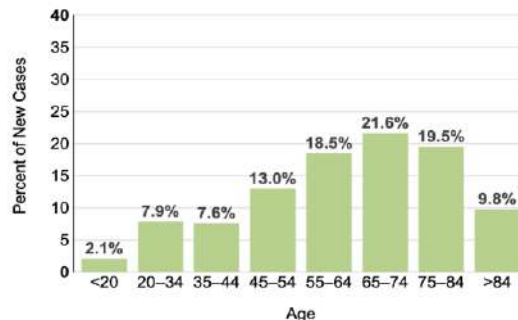
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Percent of new cases by age group



Percent of New Cases by Age Group: Chronic Myeloid Leukemia



Chronic myeloid leukemia is most frequently diagnosed among people aged 65-74.

Median Age
At Diagnosis

65

SEER.cancer.gov. 2003-2017



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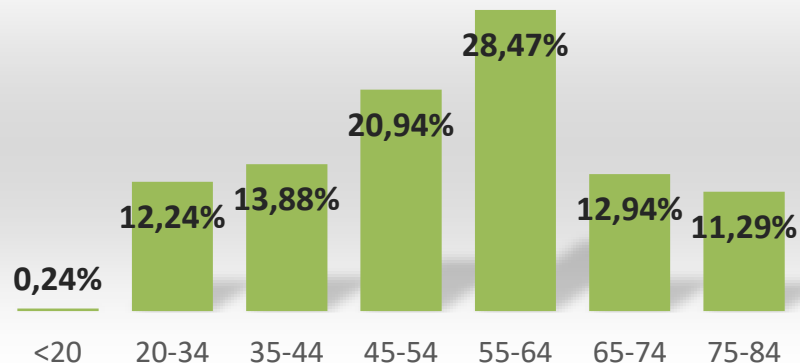


TABLE 1 Sociodemographic and clinical characteristics of patients with chronic myeloid leukemia treated at the National Cancer Institute – Mexico (2000-2016, N = 411)

Variable	N	%
Age, y		
≤40	208	50.6
41-50	103	25.0
51-60	63	15.3
>60	37	9.0

2019. Cancer Medicine. Prognostic factors in Mexican population treated with Imatinib.



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PATIENT CHARACTERISTICS	N= 425
Age at diagnosis yrs. (mean, SD)	54 (15.19)
Gender (M/F)	248/177
Insurance type (Contributory/subsidized/other)	336/57/32
Phase at diagnosis (%) (Total evaluated=387)	
Chronic	357 (92%)
Accelerated	22 (5,98%)
Blastic	8 (2%)
Sokal risk (%) (Total evaluated=232)	
Low	65 (28%)
Intermediate	81 (34,9%)
High	86 (37%)

*Not known for 38 patients



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Table 1. Base-Line Characteristics of the Patients.*

Characteristic	Imatinib (N=553)	Interferon Alfa plus Cytarabine (N=553)
Age		
Median — yr	50	51
Range — yr	18–70	18–70
≥60 yr — no. (%)	114 (20.6)	128 (23.1)
Sex — no. (%)		
Male	341 (61.7)	310 (56.1)
Female	212 (38.3)	243 (43.9)
ECOG performance status — no. (%)		
0	425 (76.9)	409 (74.0)
1	115 (20.8)	121 (21.9)
2	8 (1.4)	11 (2.0)
Data missing	5 (0.9)	12 (2.2)
Interval since diagnosis — mo		
Median	2.1	1.8
Range	0.0–10.4	0.0–8.0
Sokal risk group — no. (%)		
Total evaluated	383 (69.3)	394 (71.2)
Low	201 (52.5)	190 (48.2)
Intermediate	111 (29.0)	117 (29.7)
High	71 (18.5)	87 (22.1)

IRIS; N Engl J Med 2003;348:994-1004



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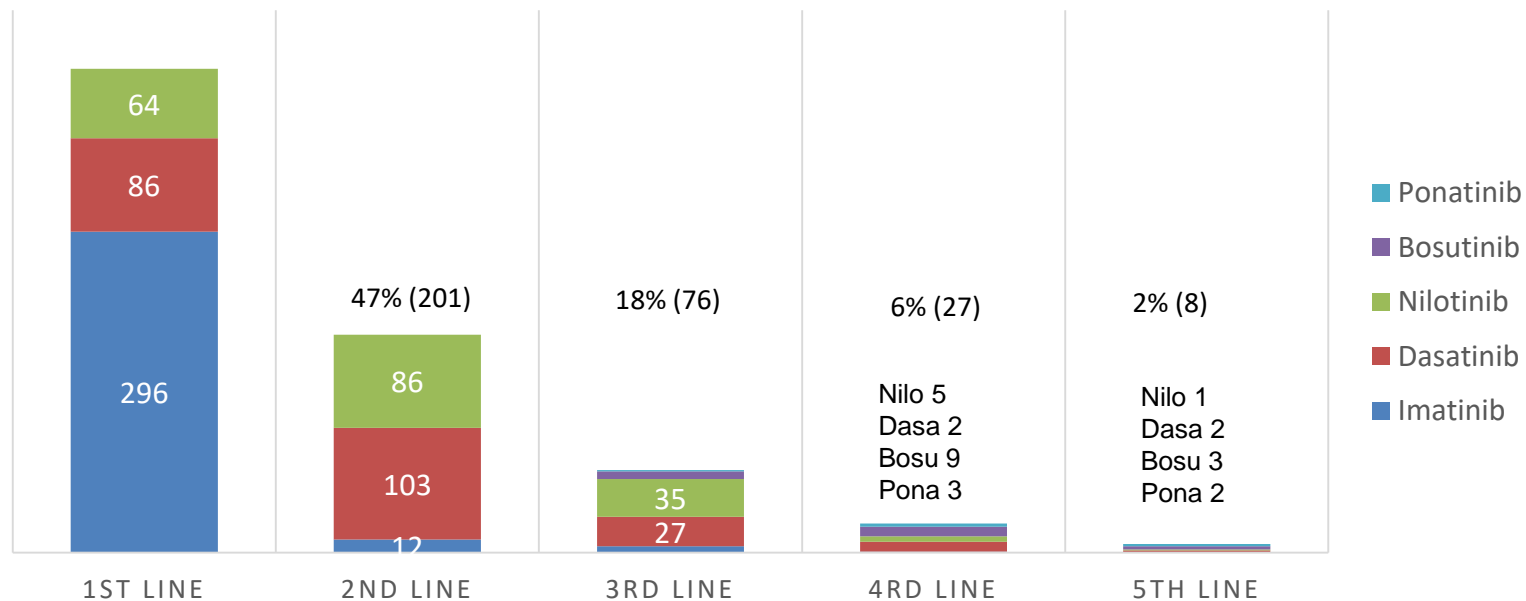
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TKI DISTRIBUTION BY LINE (N=425)

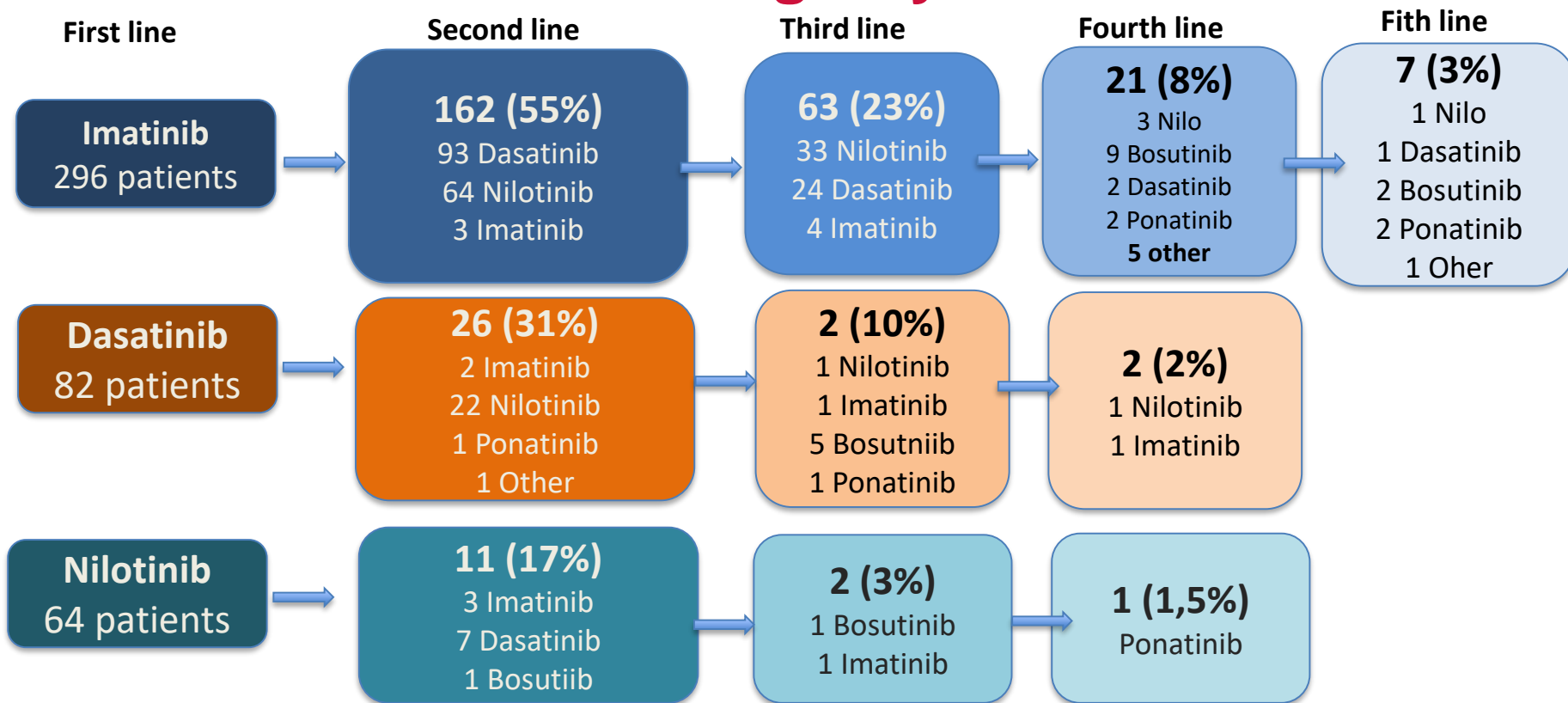


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TIME LINE IN CML PATIENTS IN COLOMBIA

- Median Follow-up: 63 months (IQR 27-108)
- Time from symptoms to **diagnosis**: 4.5 weeks (IQR 0-11)
- Time from treatment to **Complete Hematologic Response**:
Median 5 weeks (IQR 0-11)
- Time from treatment to **Complete Cytogenetic Response**: 4.1
months (IQR 12-29)
- Time from treatment to **Mayor Molecular Response**: 8.65
months (IQR 23-55)



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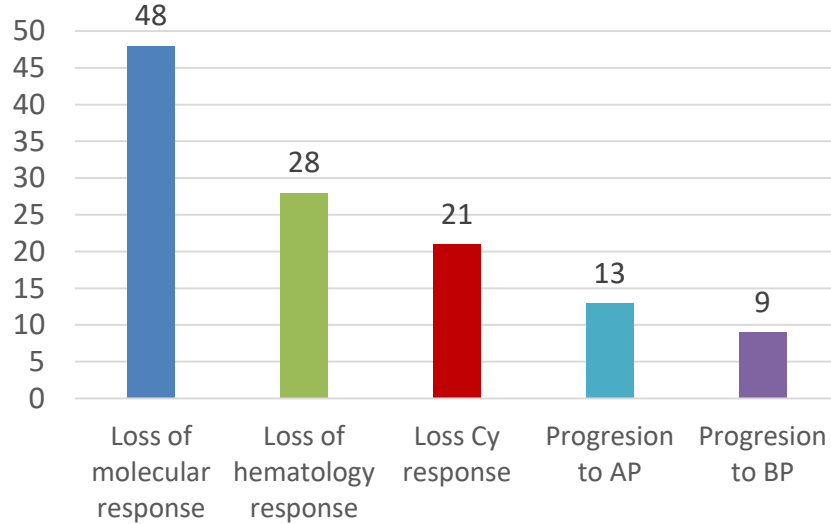
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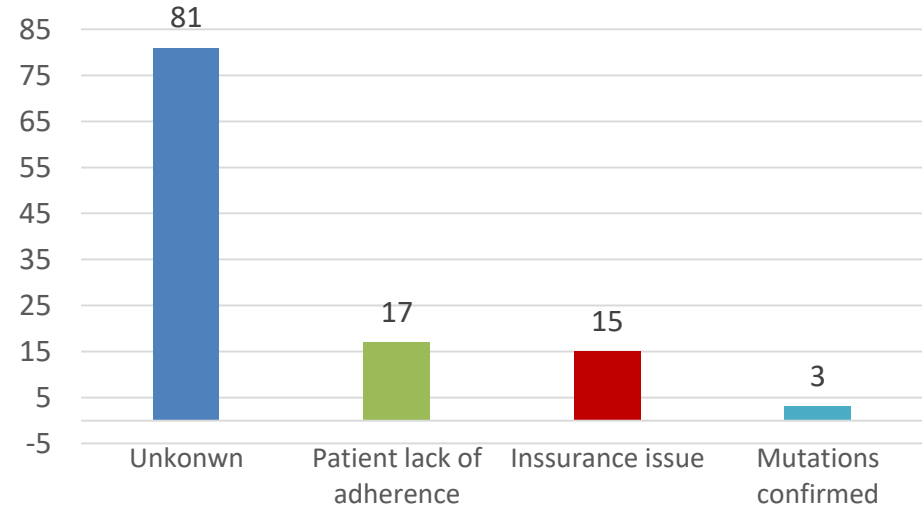
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**Type of failure to first line TKI
(No=120)**



**Investigator assessment of cause of
failure to first line TKI (No=120)**



120 (28.2%) patients failed first line treatment



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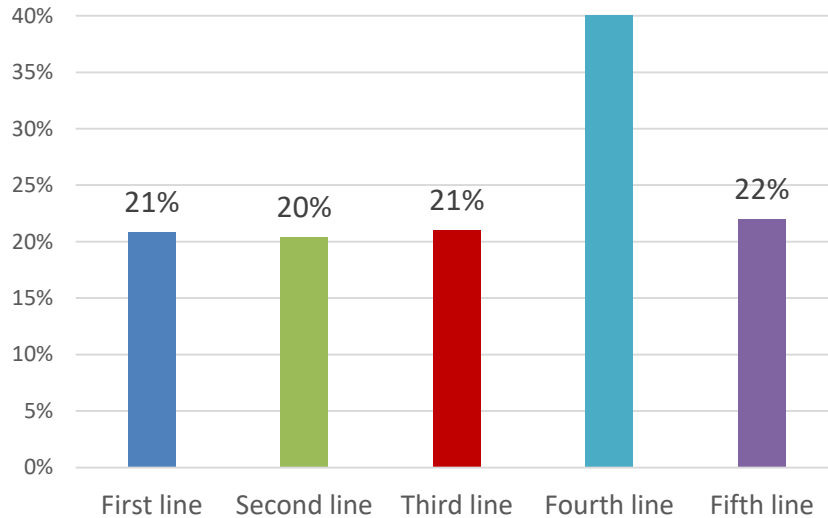
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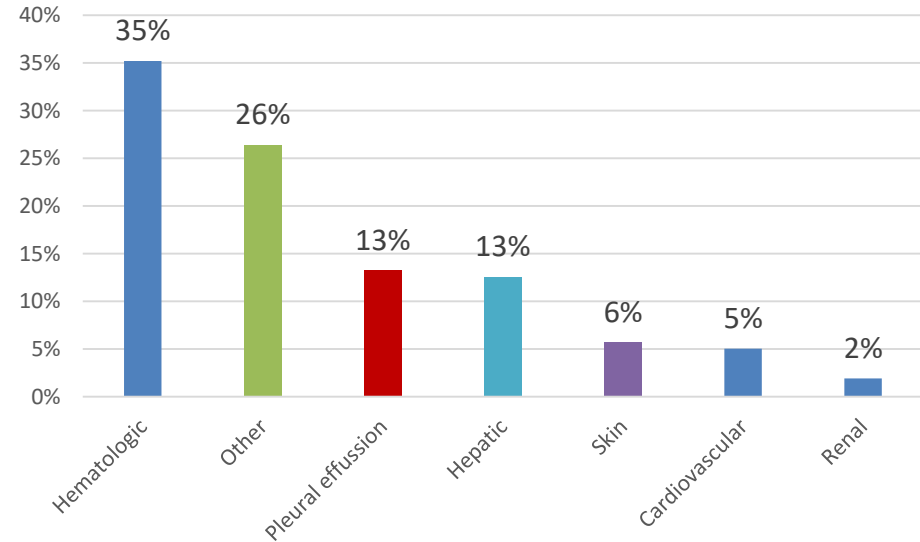
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Toxicity to TKIs (No=159)



Type of Toxicity any line of treatment (No=159)



159 (37%) patients experienced toxicity to TKIs



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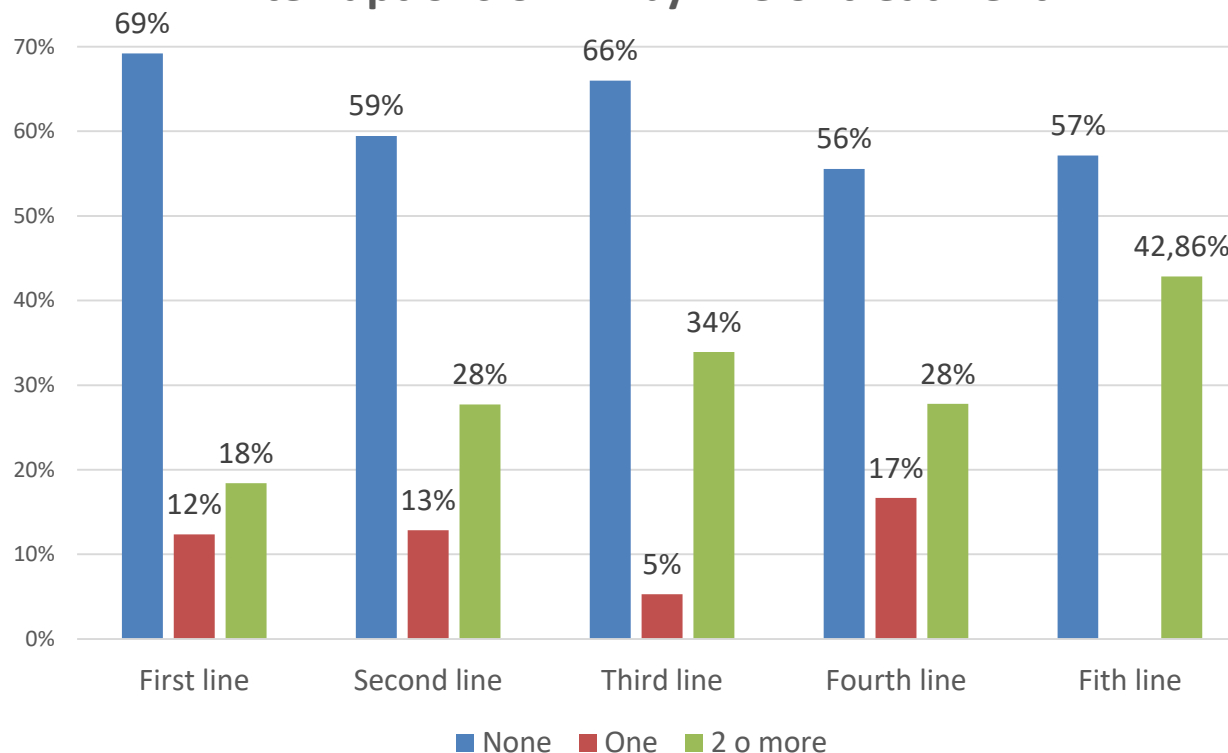
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Interruptions of TKI by line of treatment



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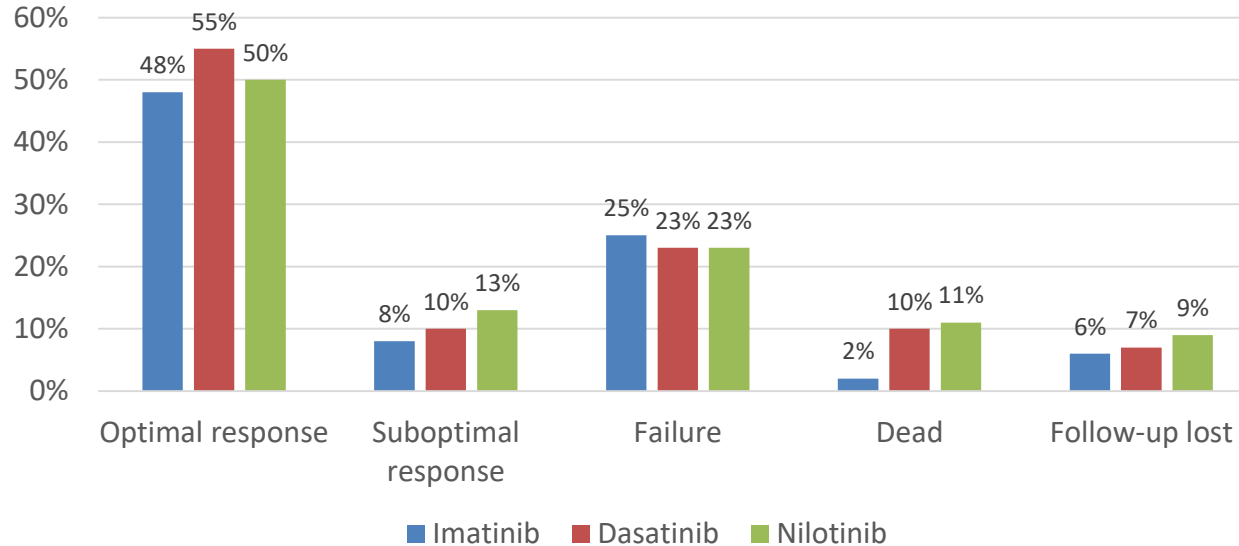
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Status at last visit by first line TKI (No=425)



Optimal response: Complete hematologic response+complete Cy Response+Mayor Molecular Response, Deep molecular response, or Treatment free remission.

Sub-optimal response: Complete hematologic response+complete Cy Response without Mayor Molecular Response

Failure: No hematologic response in chronic, blastic or accelerated phase



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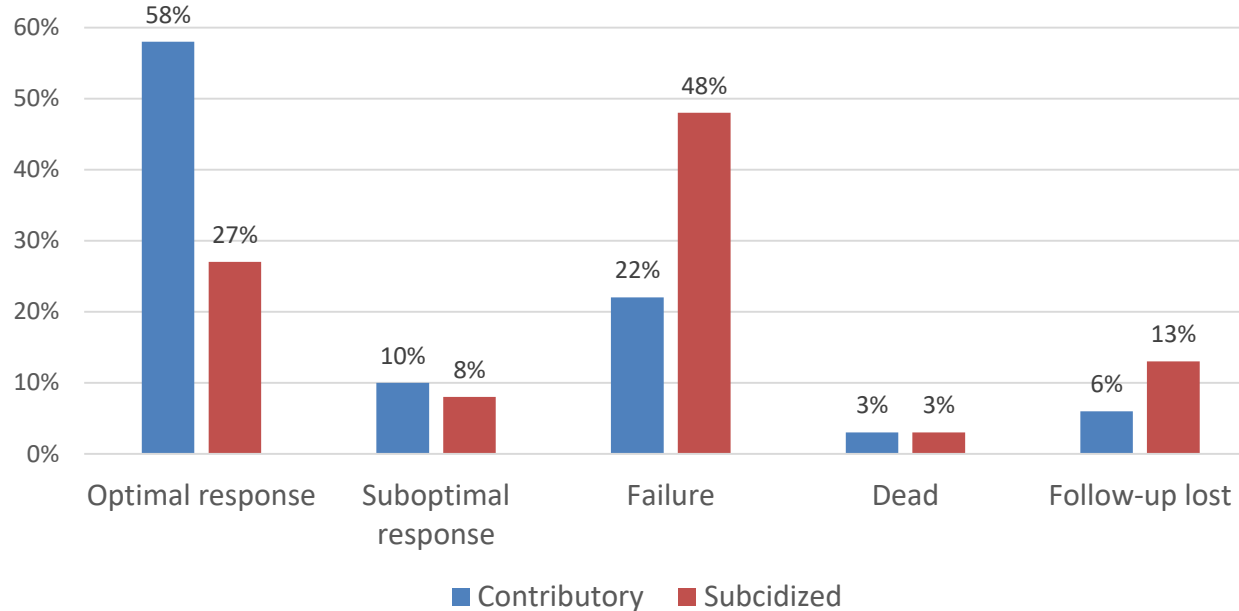
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Status at last visit by insurance regimen (No=425)



Optimal response: Complete hematologic response+complete Cy Response+Mayor Molecular Response, Deep molecular response, or Treatment free remission.

Sub-optimal response: Complete hematologic response+complete Cy Response without Mayor Molecular Response

Failure: No hematologic response in chronic, blastic or accelerated phase



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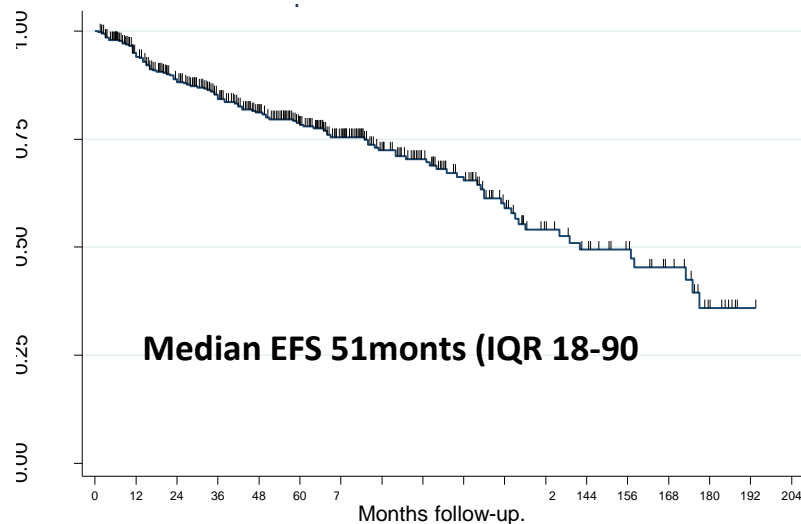
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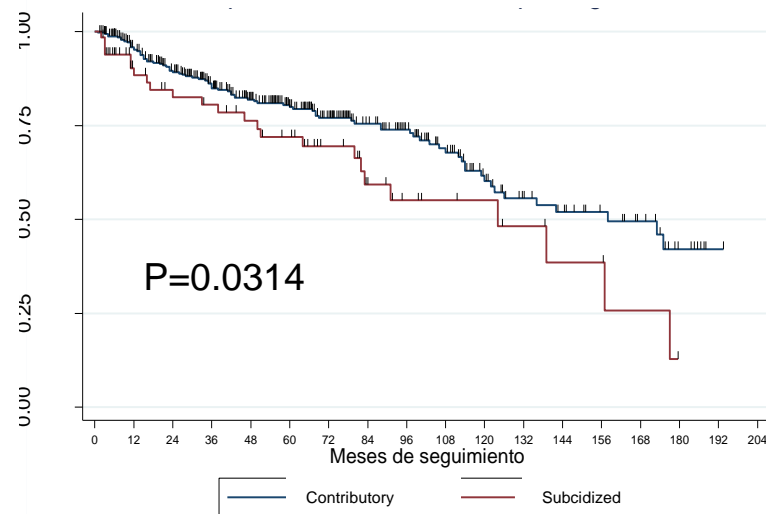


EVENT FREE SURVIVAL (No= 425)



* **EVENTS:** Death, progression to BP/AP, loss of response to TKIs.

EVENT FREE SURVIVAL BY INSURANCE SYSTEM



Contributory:

Median EFS 53monts (IQR 22-93)

Subsidized system:

Median EFS 43monts (IQR 10-99)



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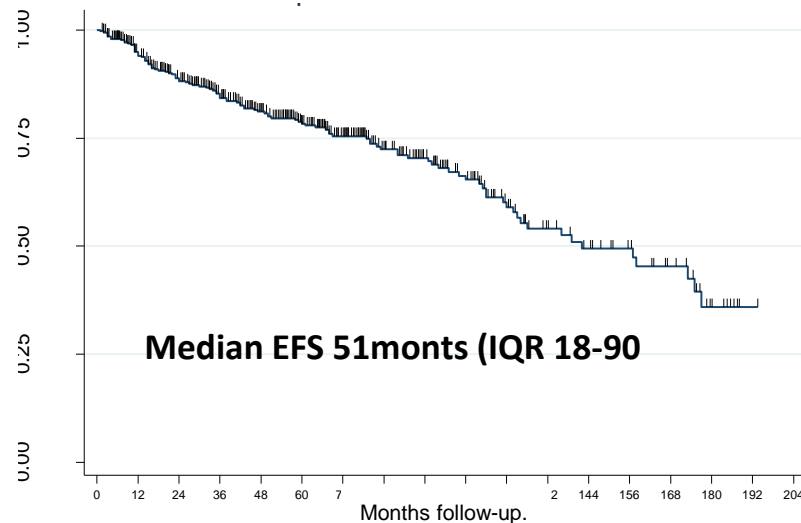
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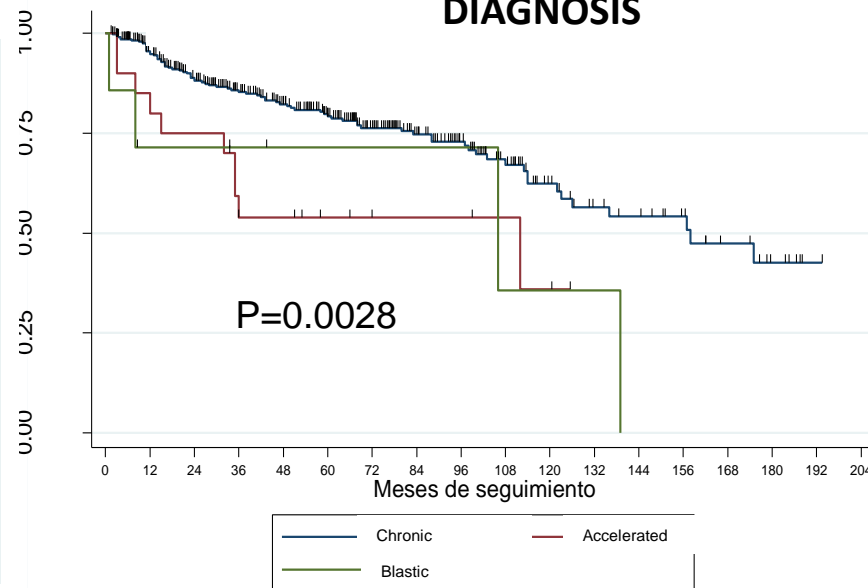


EVENT FREE SURVIVAL (No= 425)



* **EVENTS:** Death, progression to BP/AP, loss of response to TKIs.

EVENT FREE SURVIVAL BY PHASE AT DIAGNOSIS



Chronic: Median EFS 49 months (IQR 17-84)

Accelerated: Median EFS 35 months (IQR 12-66)

Blastic: Median EFS 20 months (IQR 4.5-74.5)



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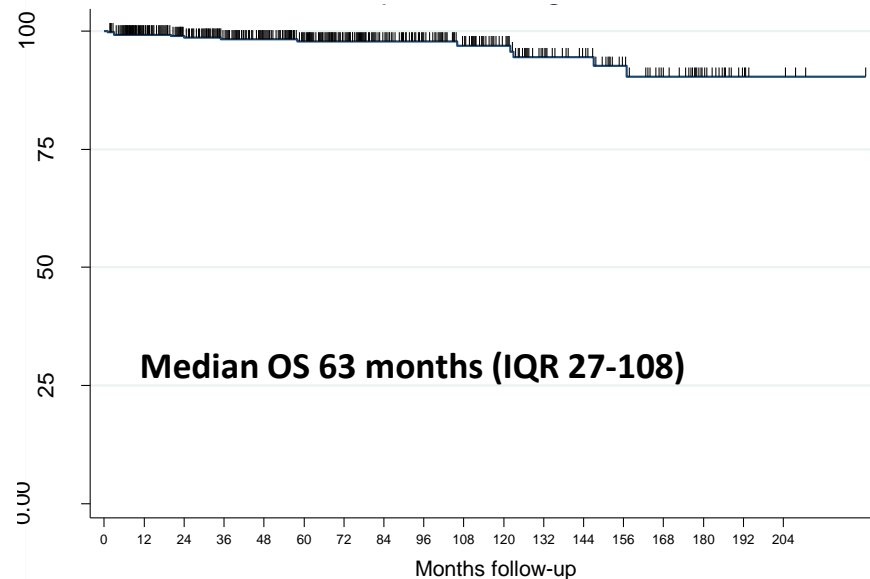
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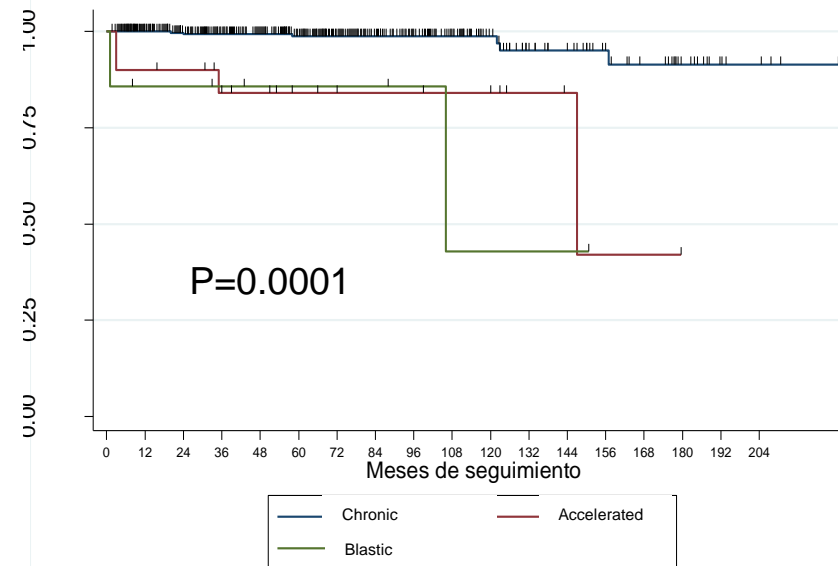
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OVERALL SURVIVAL (No= 425)



OVERALL SURVIVAL BY PHASE AT DIAGNOSIS



Chronic: Median OS 60 months (IQR 24-100)

Accelerated: Median OS 52 months (IQR 20-120)

Blastic: Median OS 38 months (IQR 4.5-97)



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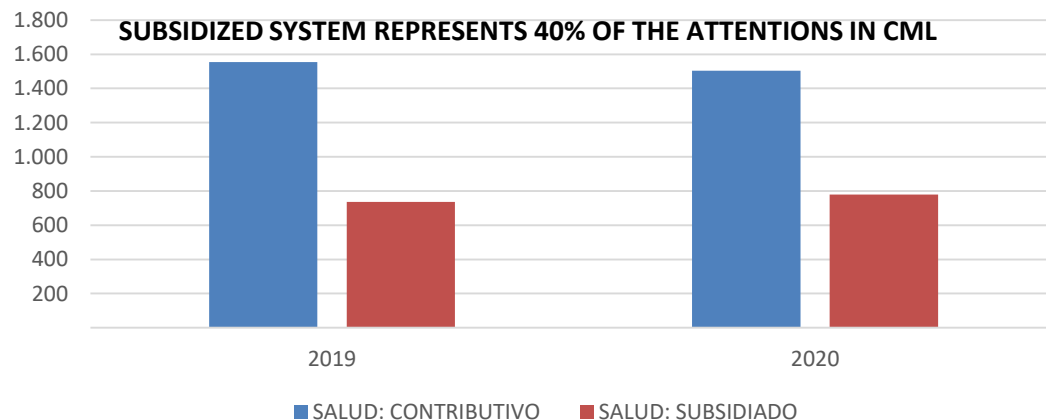


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RENEHOC LIMITATIONS

2019-2020 attentions distribution Contributory vs subsidized health insurance (Colombia)



In RENEHOC subsidized system is underrepresented

CONTRIBUTORY SYSTEM: 79%

SUBSIDIZED SYSTEM: 13%

SPECIAL INSURANCE: 8%

* SISPRO consulted December 2020



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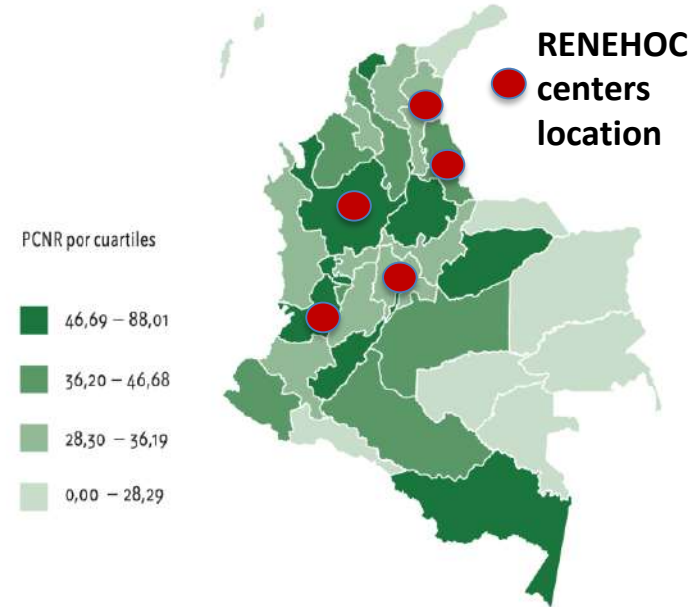
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RENEHOC LIMITATIONS

RENEHOC includes centers and investigators in big academic facilities in 5 cities (Bogotá, Medellín, Cali, Bucaramanga, Valledupar); community practice and smaller cities are underrepresented.

Distributuon of new cancer cases Colombia 2019



Incluye todos los casos nuevos de cáncer invasivo reportados a la CAC, sin discriminar por sexo, edad o tipo de cáncer.

PCNR calculada por 100,000 habitantes.



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RENEHOC HIGHLIGHTS

- It is the first multicenter registry focused on CML outcomes in Colombia.
- It will allow us to know our reality and outline relevant research questions for Colombia.
- It allows us to show realities of our country that must be corrected (inequity of access to the contributory and subsidized regimen).
- It's growth potential is evident.



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CONCLUSION (1)

- At a median follow up of 63 months (IQR 27-108), OS for CML is excellent (97%).
- The only factor predictive of OR was phase at diagnosis.
- Type of insurance and phase at diagnosis were both statistically significant predictive of EFS.
- Inequal access to TKI impacts response in CML patients; subsidized system patients had worst responses at last visit and EFS.
- There were not other independent prognostic markers for outcome.



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CONCLUSION (2)

- Population-based studies provide real world data and are important complement to data from randomized trials.
- Observational studies from population-based registries can improve the epidemiological knowledge and can also describe unknown problems that need further investigation in randomized trials.
- RENEHOC needs to expand to cover more centers, investigators and patient the represent other realities in Colombia.



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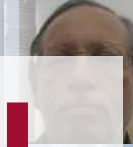
Iván Perdomo

Luis Salazar

THANK YOU

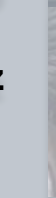
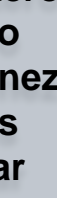
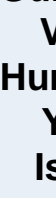
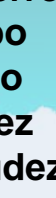
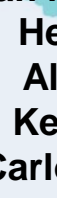
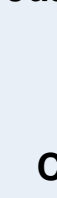
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William Mantilla

Carmen Rosales



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