V137 SIOP19-1149 Expansion of a Childhood Cancer Clinical Outcomes Surveillance System in Colombia: Challenges and Opportunities

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Background/Objectives: Assessing childhood cancer clinical outcomes and its determinants is essential for designing effective strategies to improve survival. In 2009, we established a childhood cancer clinical outcomes surveillance system (VIGICANCER) in Cali, Colombia. Since geographical location and local settings may affect outcomes, we expanded VIGICANCER to other Colombian regions to understand local differences. We describe the challenges and opportunities during expansion.

Design/Methods: We implemented VIGICANCER in Cali from 2009-2012 and, in 2013, we expanded it to 8 cities, supported by Cali's Population-Based Cancer Registry and pediatric oncologists (PO) locally. Our expansion was multi-step and based on standardized operational procedures but allowed flexible adaptations to local needs across regions. Our model includes: a PO leader in each pediatric oncology unit (POU), clinical monitors (CM) collecting data, centralized iterative quality controls and database management/reporting tailored to each region. We established a non-governmental organization (NGO) for management and financial sustainability.

Results: During 2013-2018, we expanded VIGICANCER to an area covering ~50% of Colombian children. As of December 2018, 4127 children were registered. A shared vision of the project's impact; collective trust among all stakeholders; and enhanced communication by a dedicated, reliable local leader were pivotal to a successful regional implementation. Key activities/opportunities to expansion success included: engaged POs; a committed scientific team; effective project management by the NGO; and external mentoring and funding. Capacity building was essential as POUs had no previous outcomes research experience. Local leaders were empowered to build each team. POs and CMs received systematic orientation and ongoing intensive training. To ensure process fidelity at all sites, a CM leader oversees all CMs, and regular, centralized database quality controls were performed.

Conclusions: Our multi-step model was successful in establishing and scaling a clinical outcomes pediatric cancer surveillance system in a middle-income country, which will inform cancer control efforts.

0554 / #761 Disparities in Childhood Acute Lymphoblastic Leukemia Survival in Cali, Colombia: Trend Over Ten Years From Vigicancer

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Background and Aims: Acute Lymphoblastic Leukemia (ALL) is the most common and most curable childhood cancer. However, significant disparities in survival between – and within-countries persist. Universal healthcare coverage has been proposed as a strategy to improve survival in non-communicable diseases. In 2010, childhood cancer became a health priority for Colombian public health agenda. We describe ALL survival disparity trends over 10 years within a universal healthcare system in Cali, Colombia's third-largest city.

Methods: We prospectively collected data from Cali's Childhood Cancer Surveillance System (VIGICANCER), supported by "My Child Matters" since 2009. We included patients <15 years with newly-diagnosed ALL. We compared 5-year overall (OS) and event-free survival (EFS) from 2009-2013 (cohort A [CA]) to 2013-2018 (cohort B [CB]). We used Kaplan-Meier and Cox regression methodology for survival analyses and covariate adjusting.

Results: Six-hundred-and-thirty-four patients were included, CA 237, and CB 397. There were no significant differences between cohorts in age, sex, residence, insurance groups (public, semi-private), cell linage type, testicular involvement, or risk groups. Five-year OS in the public insurance group improved from 47% to 68% (CA vs. CB; $p < 0.01$) and 5-year EFS increased from 38% to 57% (CA vs. CB; $p<0.01$). The OS and EFS gap between semi-private and public health insurance decreased by 50% between cohorts. Survival differences remained significant in multivariate analyses.

Conclusions: Both 5-year OS and EFS significantly improved in patients with ALL covered by public insurance. This improvement could be attributed, in part, to enhancements in cancer care in Cali over the last 5 years, including increased childhood cancer awareness among healthcare providers, decrease in fragmentation of services, expanded access to high-quality hospitals for patients with public insurance coverage, improved supportive care, better social support, and newly-implemented care navigation services. Future research is needed to determine factors as significant predictors of survival. Supported by Sanofi-Espoir-Foundation-"My Child Matters"-Program

O0099 / #281 Childhood Cancer Survival Gap by Health Insurance Type in Colombia: A Report from Vigicancer Surveillance System

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Background and Aims: Since 1993, Colombia, a middle-income country, shifted to a universal healthcare system with current coverage of more than 95% of its inhabitants. Herein, we describe pediatric cancer survival gaps by health insurance type in nine large Colombian cities.

Methods: We included prospectively collected data of children (<15 years) from VIGICANCER (Childhood Cancer Outcomes Surveillance System) from nine cities with a mean population of 1.8 million inhabitants (range: 0.35 to 7.7 million). We grouped cities with >100 cases/year (3 cities) or <100 cases/year (6 cities). We used Kaplan-Meier for survival analyses and Cox regression to adjust the hazard ratios (aHR) by covariates (age, sex, ethnicity, residence, city group, and tumoral group).

Results: From 2013 to 2019, 2431 children were registered in the 9 cities. Patients' median age was 6 years, 56% were male, 36% resided in a province capital, and 8% were afro-Colombians. Ninety-six percent of patients had health insurance coverage. Insurance type was semi-private in 40%, public in 51%, and other (military/police/teachers) in 5%. Cohort 5-year overall survival (OS) was 58% (95% CI: 56, 61); 61% for hematological malignancies, 46% for brain tumors, and 58% for extra-cranial solid tumors. Semi-private vs. public OS gap at 2, 3, and 5 years was 6%, 8%, and 11%, respectively; $p<0.001$. The aHR of mortality for public compared to semi-private insurance was 1.4 (95% CI: 1.2, 1.7).

Conclusions: We show that the pediatric cancer OS gap by health insurance type in Colombia is a widespread phenomenon despite city size and region. Determinants of pediatric cancer survival are complex and insurance coverage plays a pivotal role. Although achieving universal health coverage is an immense public health advancement, it seems that is not sufficient to improve outcomes and additional measures must be taken to address pediatric cancer survival gaps.

PV0321 / #274 Childhood Central Nervous System Tumors Characteristics and Survival in Ten Colombian Cities

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Background and Aims: Data on overall survival (OS) for central nervous system (CNS) tumors in children in low-and-middle income countries (LMIC) is scarce. We describe clinical characteristics and OS of children with CNS tumors in ten Colombian cities.

Methods: We analyzed prospectively collected data from 2009 to 2020 of children (<15 years) with primary CNS tumors included in VIGICANCER (Childhood Cancer Outcomes Surveillance System established in 2009 with the Sanofi-Espoir-Foundation support) currently operating in ten Colombian cities. VIGICANCER does not include craniopharyngiomas, and germ cell tumors were excluded from this analysis. We used the Kaplan-Meier method for survival estimates.

Results: During the study period, 764 CNS tumors were diagnosed in 5063 children with cancer. Cohort median age was 7.5 years, 55% were males, and 10% afro-descendants. The cerebrum was involved in 48%, cerebellar in 27%, brain stem (BST) in 14%, and other brain structures/spinal cord in 11%. Pathology diagnoses were comprised of 29% supratentorial gliomas, 26% embryonal CNS tumors (medulloblastoma in 80%), 20% gliomas in other locations, 11% ependymomas, 4% neuroglial, 2% pineal, 1% neuroepithelial, and 7% other. Cohort 5y-OS was 44% (95%CI: 39, 48), and in less than 3 years of age 5y-OS was 36% (95%CI: 26, 47). OS improved from 36% (2009-2013) to 46% (2014-2020); p=0.001. Five-year OS were 85% (95%CI: 72, 92), 59% (95%CI: 41, 73) and 14% (95%CI: 6, 26) for grade I, grade II and grade III/IV supratentorial gliomas, respectively. Five-year OS for medulloblastoma and brain stem tumors were 46% (95%CI: 35, 56) and 8% (95%CI: 2, 18), respectively.

Conclusions: Our results contribute to the limited data on childhood CNS survival in LMIC. We found a significant increase in OS from 2014-2020 compared to 2009-2013. This survival improvement is modest compared to advances in high-income countries, achieving 5y-OS of 70 to 75% in malignant CNS tumors.

O288 / #1721 END OF INDUCTION MEASURABLE RESIDUAL DISEASE AND EARLY EVENT-FREE SURVIVAL IN B-CELL CHILDHOOD ACUTE LYMPHOBLASTIC LEUKEMIA: A REAL-WORLD EXPERIENCE IN COLOMBIA

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Background and Aims: Measurable residual disease (MRD) at the end of induction therapy (EOI) is a strong survival predictor in childhood acute lymphoblastic leukemia (ALL). In middle-income countries (MIC), validity has not been systematically assessed, which is the first step for MRD routine implementation in clinical practice. We assessed the prognostic capability of MRD evaluation at EOI in a B-ALL cohort in Colombia.

Methods: We prospectively collected data in children (<15 years) with ALL in ten Colombian cities included in VIGICANCER (Childhood Cancer Surveillance System). In Colombia, MRD is performed by multiparametric flow cytometry (FACS), following EuroFlow protocols and performed at different institutions without central review or validation. We assessed the performance of EOI MRD and associated event-free survival (EFS) by using Kaplan-Meier and Cox regression methods.

Results: During the study period (2019-2021), 871 patients with B-ALL were included, with median age of 5.5 years (IQR: 3,10). Fifty-two percent were male and 9% were afro-descendants/native-Colombians. Negative MRD (<0.01%) was reported in 74% of patients, low (0.01-0.09%) in 19%, intermediate (1.00-4.99%) in 4% and high (≥5%) in 3%. MRD results were unavailable in 12% of patients. Six hundred ninety-seven patients with EOI MRD contributed to the survival analysis. Twenty-four-months EFS was 89% (95%CI: 85, 92), 68% (95%CI: 56, 77), 41% (95%CI: 18, 62), and 37% (95% CI: 11, 64) in patients with negative MRD, low MRD, intermediate MRD and high MRD, respectively (P-value <0.001). Adjusted hazard rates were 2.7 (95%CI: 1.7, 4.2) for low MRD, 6.1 (95%CI: 3.1, 12.2) for intermediate, and 3.9 (95%CI: 1.9, 8.4) for high. Cumulative mortality at EOI was 6%.

Conclusions: Despite diagnosis capabilities constraints in Colombia, EOI MRD, as measured with FACS, retains its prognostic significance. Our findings support the development of standardized treatment strategies, that include EOI MRD evaluation for risk stratification of B-ALL, in our country and other MIC.

EP058 / #1663 LOW FREQUENCY OF T(12;21) B-CELL ACUTE LYMPHOBLASTIC IN COLOMBIA: A REPORT FROM VIGICANCER WORKING GROUP

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Background and Aims: Children with acute lymphoblastic leukemia (ALL) and t(12;21) (ETV6-RUNX fusion) have excellent overall survival. Prevalence in children is approximately 20-25%, however reports suggest prevalence has geographical and ethnic variability. We assessed the prevalence of t(12;21) in children with ALL from Colombia.

Methods: We conducted a cross-sectional study to estimate the prevalence of the t(12;21) in patients with newly diagnosed B-cell ALL (<15 years of age) included in 27 pediatric oncology units (POU) in 10 Colombian cities reporting to VIGICANCER (Childhood Cancer Surveillance System). In Colombia, detection of t(12;21) is performed by fluorescence in situ hybridization (FISH) at several commercial laboratories; however, no centralized validation is carried out.

Results: From January 2019 to December 2021, VIGICANCER included 965 children with ALL (871 B-cell, 80 T-cell; 14 mixed/unclassified). In the B-cell ALL cohort, the median age was 5.5 years (IQR: 3, 10), 52% were male, 9% were afro-descendants and/or native Colombians, and 50% had public insurance. FISH for t(12;21) was performed in 67% of patients and for t(9;22) in 83%. Frequencies for t(12;21) and t(9;22) were 11% (95%CI: 8, 13) and 5% (95%CI:3, 7), respectively. We found an 8% prevalence of t(12;21) in patients with public health insurance vs. 14% in semi-private (P=0.02). There was high heterogeneity in detection among the different POUs, and in two, the prevalence was 20-28%

Conclusions: Prevalence of t(12;21) in B-cell childhood ALL in a sizeable sample of patients in Colombia was lower than reported in other regions. Two POUs achieved the expected prevalence reported in high-income countries. There were differences by insurance, suggesting that the low prevalence in our sample could be related to the quality of FISH methodology used in Colombia. Our findings impact the survival of Colombian children and present an opportunity to improve ALL diagnosis, classification, and treatment in resource-constrained settings by developing targeted strategies.

SURVIVAL IMPROVEMENT OF CHILDREN WITH ACUTE LYMPHOBLASTIC LEUKEMIA AND TREATMENT ABANDONMENT IN CALI, COLOMBIA

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Background and Aims: Treatment abandonment (TxA) remains a challenge in low-and-middle-income countries (LMIC). Children with acute lymphoblastic leukemia (ALL) and TxA have poor overall survival (OS). SIOP defined TxA as ≥4 weeks of therapy interruption not due to medical reasons. To improve outcomes for children with ALL after TxA, we developed treatment guidelines for this subgroup. We describe the 5-year OS for children with ALL and TxA, pre- and post-guideline implementation.

Methods: Treatment guidelines were implemented in 3 pediatric oncology units (POU) in Cali, Colombia and included individualized intensity based on risk, relapse status, and minimal residual disease upon return to the POU after TxA. We analyzed data from 2009 to 2020 in children (<15 years) with ALL included prospectively in VIGICANCER (Childhood Cancer Outcomes Surveillance System). We compared 5-year OS for children with ALL and TxA pre-guideline implementation (Pre:2009-2013) and post-guideline implementation (Post:2014-2020). We used Kaplan-Meier and Cox regression for adjusted survival analyses.

Results: During the study period, 743 children with ALL were diagnosed in Cali and registered in VIGICANCER; Pre=296, and Post=447. Patients with T-cell phenotype and NCI high-risk were balanced pre- and post-implementation (9% vs 10%, and 44% vs 46%, respectively). We did not find differences in the 2-year cumulative incidence of TxA (pre=11% vs post=9%; p=0.14). Five-year OS in children with ALL and TxA pre-implementation (n=31) was 36% (95%CI:19,52) compared to 73% (95%CI:51,86) in children with ALL and TxA post-implementation (n=27); p=0.01. This OS difference was independent of potential confounders.

Conclusions: We found a 37% absolute increase in the 5-year OS between children with ALL and TxA pre- and post-guideline implementation. Our findings suggest that tailored, individualized chemotherapy regimens for children with ALL and TxA may improve survival. Further research is warranted to test the efficacy of this tailored approach, which could potentially improve OS in LMIC.

RADAR: A RISK SCORE ASSESSMENT FOR PREDICTING TREATMENT ABANDONMENT IN CHILDHOOD CANCER IN COLOMBIA

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Background and Aims: Cancer treatment abandonment (TxA) is a major factor for relapse. Assignment of TxA risk at diagnosis allows for early interventions to prevent TxA. We developed **RADAR**, a TxA risk score. Here we describe RADAR's performance.

Methods: To construct RADAR, we selected potential predictors from a systematic literature review. To train and test the models, we used data from children (<15 years) with a new diagnosis of childhood cancer from ten Colombian cities enrolled prospectively in our Childhood Cancer Surveillance System (VIGICANCER), during 2009-2020. We used multivariate Cox's regression stratified by city and diagnosis period, competing risks models, and logistic regression. We choose the final predictors by the backward stepwise method and by using Lasso regression with cross-validation. Lastly, bootstrapping was used to evaluate the robustness of the predictors.

Results: The cohort included 5,442 patients and 335 TxA events. Cumulative incidence of TxA at 24 months was 9% (95%CI: 8, 10). The score included the following predictors: insurance type, rural residence, and residence in a province without a pediatric oncology unit. We classified risk in 3 categories: low (<3%), intermediate (3 to 6%), and high (>6%). Twelve-months probability of TxA for the minimum score (1) was 2% and for the maximum score (7) was 12%. The area under the receiver operating characteristics curve (ROC) at 3 months was 0.74 and at 24 months 0.69.

Conclusions: RADAR showed a 70% probability of distinguishing between TxA cases and non-TxA cases, with only a minor decline in performance of its prediction capacity over time. RADAR uses only three predictors at diagnosis for TxA risk, contributing to simplicity and feasibility, which are key attributes for successful implementation in clinical settings. RADAR is currently applicable in Colombia. Next steps involve further validation and adaptation to other Latin-American countries.

EARLY MORTALITY IN MALIGNANT BONE TUMORS DURING THE COVID-19 PANDEMIC IN A MIDDLE-INCOME COUNTRY

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Background and Aims: The COVID-19 pandemic impacted the population's social and economic conditions and vastly affected health systems' capabilities for effective care delivery. In low-and-middle-income countries (LMIC), COVID-19's impact on childhood cancer mortality is unknown. We investigated COVID-19's effect on early mortality in children with bone tumors in ten cities in Colombia.

Methods: We prospectively collected data from children (<15 years) included in the Childhood Cancer Outcomes Surveillance System (VIGICANCER) from 2017 to 2021. The "COVID-19 pandemic period" included cases diagnosed 2020-2021. Children diagnosed with cancer during the study period were the exposed cohort (EC). Using Kaplan-Meier, we compared the cumulative mortality rate and survival in the EC with a historical cohort (HC; 2017-2019). We adjusted the hazard ratio estimates (HRa) for covariates using proportional risks multivariate regression.

Results: From 4197 children enrolled in VIGICANCER during the study period (EC 1692, HC 2505), 251 were diagnosed with a malignant bone tumor (EC 104, HC 147). Osteosarcoma was diagnosed in 63% (n=157; EC 70, HC 87), Ewing sarcoma in 31% (n=79; EC 26, HC 53), and other in 6% (n=15; EC 8, HC 7). Ninety-three cases (37%) were metastatic, with no differences between cohorts (EC 41% vs HC 34%; p=0.29). Children with bone tumors in the EC showed an increased risk of death at 6 months post-diagnosis (HRa=3.4 95%CI:1.2, 10.1) and at 24 months post-diagnosis (HRa=1.7, 95%CI: 1.1, 2.8). The association of the EC with 6-months mortality decreased but persisted when including metastatic status (HRa=2.9 95%CI: 1.0, 8.7).

Conclusions: We found a three-fold increase in mortality risk at 6 months post-diagnosis in children diagnosed with bone tumors during the COVID-19 pandemic. This association remained in children with metastasis, suggesting other causal pathways to mortality. Next steps include investigation of COVID-19's effects in other tumors and follow-up analysis to assess long-term effects of COVID-19 on survival.