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Original Research Article

Precision Chemotherapy: Towards Personalized Cancer Treatment

Quimioterapia de Precisión: Hacia un Tratamiento Personalizado del Cáncer

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ABSTRACT

Precision chemotherapy represents a paradigm shift in oncology, tailoring cytotoxic regimens to molecular tumor profiles to improve efficacy and reduce toxicity. A multicenter observational study was conducted in Mexico and Ecuador with patients diagnosed with breast, colorectal, ovarian, and cervical cancers. Clinical and demographic data were collected, and molecular profiling was performed using tissue-based next-generation sequencing (NGS) and plasma-derived circulating tumor DNA (ctDNA). Outcomes included objective response rate (ORR), progression-free survival (PFS), overall survival (OS), toxicity, and patient-reported quality of life (QoL). High concordance above 80% was observed between NGS and ctDNA for key biomarkers, with BRCA1/2 and MMR/MSI alterations associated with superior ORR, PFS, and OS, whereas KRAS mutations correlated with poorer outcomes. Biomarker-guided chemotherapy significantly reduced grade ≥3 adverse events compared with conventional regimens and improved QoL scores by 8–10 points across functional domains (EORTC QLQ-C30). These findings confirm that precision chemotherapy enhances efficacy, tolerability, and patient-centered outcomes, while the binational experience in Mexico and Ecuador highlights both feasibility and the urgent need for equitable access to molecular diagnostics in Latin America. Precision chemotherapy should be prioritized as a central component of global cancer control strategies.

keywords: precision oncology; chemotherapy; biomarkers; liquid biopsy; Mexico; Ecuador

RESUMEN

La quimioterapia de precisión constituye un cambio de paradigma en oncología, al adaptar los esquemas citotóxicos al perfil molecular del tumor con el objetivo de mejorar la eficacia y reducir la toxicidad. Se realizó un estudio multicéntrico observacional en México y Ecuador con pacientes con cáncer de mama, colorrectal, ovárico y cervicouterino. Se recolectaron datos clínicos y demográficos y se efectuó el perfil molecular mediante secuenciación de nueva generación (NGS) en tejido y ADN tumoral circulante (ctDNA) en plasma. Los desenlaces incluyeron tasa de respuesta objetiva (ORR), supervivencia libre de progresión (PFS), supervivencia global (OS), toxicidad y calidad de vida (QoL). Se observó una concordancia superior al 80% entre NGS y ctDNA en biomarcadores clave, con alteraciones en BRCA1/2 y MMR/MSI asociadas a mejores ORR, PFS y OS, mientras que las mutaciones en KRAS se relacionaron con peores resultados. La quimioterapia guiada por biomarcadores redujo significativamente los eventos adversos grado ≥3 frente a la convencional y mejoró en 8–10 puntos los puntajes de QoL en los dominios funcionales (EORTC QLQ-C30). Estos hallazgos confirman que la quimioterapia de precisión optimiza la eficacia, la tolerancia y los desenlaces centrados en el paciente, mientras que la experiencia binacional en México y Ecuador resalta tanto su factibilidad como la necesidad

urgente de garantizar un acceso equitativo a diagnósticos moleculares en América Latina. La quimioterapia de precisión debe priorizarse como componente central de las estrategias globales de control del cáncer.

Palabras clave: Oncología de precisión; quimioterapia; biomarcadores; biopsia líquida; México; Ecuador

RESUMO

A quimioterapia de precisão representa uma mudança de paradigma na oncologia, ao adaptar os esquemas citotóxicos ao perfil molecular do tumor com o objetivo de melhorar a eficácia e reduzir a toxicidade. Foi realizado um estudo multicêntrico observacional no México e no Equador com pacientes portadores de câncer de mama, colorretal, ovariano e do colo do útero. Foram coletados dados clínicos e demográficos, e o perfil molecular foi obtido por meio de sequenciamento de nova geração (NGS) em tecido e DNA tumoral circulante (ctDNA) no plasma. Os desfechos incluíram taxa de resposta objetiva (ORR), sobrevida livre de progressão (PFS), sobrevida global (OS), toxicidade e qualidade de vida (QoL). Observou-se uma concordância superior a 80% entre NGS e ctDNA em biomarcadores-chave, com alterações em BRCA1/2 e MMR/MSI associadas a melhores ORR, PFS e OS, enquanto mutações em KRAS se relacionaram a piores resultados. A quimioterapia guiada por biomarcadores reduziu significativamente os eventos adversos de grau ≥3 em comparação com a quimioterapia convencional e melhorou em 8–10 pontos os escores de QoL nos domínios funcionais (EORTC QLQ-C30). Esses achados confirmam que a quimioterapia de precisão otimiza a eficácia, a tolerância e os desfechos centrados no paciente, enquanto a experiência binacional no México e no Equador destaca tanto sua viabilidade quanto a necessidade urgente de garantir acesso equitativo aos diagnósticos moleculares na América Latina. A quimioterapia de precisão deve ser priorizada como componente central das estratégias globais de controle do câncer.

palavras-chave: Oncologia de precisão; quimioterapia; biomarcadores; biópsia líquida; México; Equador

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INTRODUCTION

Cancer continues to be one of the most pressing global health challenges, with an estimated 19.3 million new cases and 10 million deaths worldwide in 2020 alone (Calderón-Aparicio & Gallegos, 2019). Traditional chemotherapy remains a cornerstone of cancer treatment; however, its limitations—ranging from systemic toxicity to variable therapeutic responses and the emergence of resistance—underscore the urgent need for more precise therapeutic strategies (Caputo et al., 2023; Fernández-Lázaro et al., 2020). The concept of precision oncology has therefore emerged as a paradigm shift, aiming to match the right treatment to the right patient by leveraging molecular, genetic, and clinical information (Ma et al., 2024; González et al., 2025).

Precision chemotherapy, situated within this broader framework, represents an innovative strategy to maximize efficacy while minimizing harm. Advances in high-throughput genomic sequencing, transcriptomic profiling, proteomics, and bioinformatics have enabled clinicians to identify actionable mutations, stratify patients, and adapt cytotoxic regimens in a biomarker-guided fashion (Ruiz de Castilla et al., 2024; Ulivi, 2023). The incorporation of liquid biopsy, through circulating tumor DNA (ctDNA) and circulating tumor cells (CTCs), has become a crucial non-invasive tool for early detection of relapse, monitoring therapeutic response, and guiding dynamic treatment adjustments (Martinelli et al., 2025; Malik et al., 2025; Jamali et al., 2025). These technologies hold particular promise in solid tumors such as breast, gynecological, and colorectal cancers, where dynamic molecular changes often dictate treatment outcomes (Ma et al., 2024; Martinelli et al., 2025; Montalvan-Sanchez et al., 2024).

Equally relevant are studies that demonstrate the predictive and prognostic value of specific biomarkers for chemotherapy sensitivity or resistance. For example, genomic alterations in DNA repair genes have been

linked to platinum responsiveness, while expression signatures in transport proteins predict resistance to anthracyclines (Pando-Caciano et al., 2024; de Scordilli et al., 2025). The integration of these biomarkers into decision-making models allows the personalization of cytotoxic therapy, traditionally seen as "one-size-fits-all," transforming it into a tailored modality aligned with the unique biology of each patient (Ismael et al., 2024; Llera et al., 2023).

Despite this scientific progress, substantial inequities remain in access to precision oncology, particularly in low- and middle-income regions. In Latin America, for instance, limited infrastructure, uneven distribution of molecular diagnostics, and scarcity of specialized oncologists constrain the implementation of personalized strategies (Gomez-Abuin et al., 2025; Villarreal-Garza et al., 2025). Mexico and Ecuador exemplify both the challenges and opportunities of precision chemotherapy adoption: Mexican cohorts have demonstrated the feasibility of integrating next-generation sequencing (NGS) into clinical decision-making (González et al., 2025), while Ecuadorian studies highlight regional genetic variants in thyroid and colorectal cancers that may inform tailored therapies (Gavilanez et al., 2024). However, systemic barriers such as cost, logistics, and policy frameworks remain significant (Ruiz de Castilla et al., 2024; Sarria et al., 2022).

Collaborative initiatives and international partnerships have sought to mitigate these disparities. Reports from organizations like SLACOM and multicenter studies such as LACOG have provided consensus recommendations to optimize biomarker-driven oncology and identify gaps in health system capacity (Ismael et al., 2024; Vargas Pivato de Almeida et al., 2025). Moreover, policy reviews of national cancer control plans across Latin America and the Caribbean emphasize the urgent need for stronger integration of molecular diagnostics, workforce training, and sustainable financing models (Villarreal-Garza et al., 2025; Llera et al., 2023). These findings underscore that the problem of equitable precision oncology is not purely scientific, but also organizational, political, and socioeconomic in nature.

Within this context, the present study addresses three central research questions: (1) Can precision chemotherapy improve survival and quality of life outcomes compared to conventional regimens? (2) Which biomarkers and molecular platforms hold the greatest clinical utility across diverse tumor types and patient populations? (3) How can resource-variable settings, particularly Mexico and Ecuador, overcome structural challenges to implement precision chemotherapy? By situating these questions within a multicenter framework, the design of this study integrates molecular profiling, biomarker-driven stratification, and clinical endpoints, aiming to demonstrate the translational value of precision chemotherapy in heterogeneous populations (Personalizing Precision Oncology Clinical Trials in Latin America, 2018; Calderón-Aparicio & Gallegos, 2019).

In summary, the introduction of precision chemotherapy is not merely a scientific innovation but a necessary evolution of cancer care. By aligning methodological rigor with biomarker-driven strategies and by addressing global health inequities, this approach promises to reduce toxicity, overcome resistance, and ensure that advances in oncology translate into tangible benefits for patients worldwide (Fernández-Lázaro et al., 2020; Ruiz de Castilla et al., 2024; Montalvan-Sanchez et al., 2024). The significance of this endeavor is magnified in Latin America, where successful implementation could reshape the trajectory of cancer care, bridging gaps between innovation and access, and establishing new standards of equitable, patient-centered oncology (Gomez-Abuin et al., 2025; Villarreal-Garza et al., 2025).

METHODS

Participants

The study population consisted of adult patients with histologically confirmed malignancies for which systemic chemotherapy was indicated. Recruitment was conducted across three tertiary-level hospitals in Mexico (Mexico City and Cuernavaca) and

two oncology centers in Ecuador (Quito and Guayaquil). Eligible participants were required to be at least 18 years of age, with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2, and to present with adequate hematological, hepatic, and renal function as determined by laboratory assessments performed within two weeks prior to enrollment. Tumor types included breast, colorectal, ovarian, and cervical cancers, which were chosen due to their prevalence and the availability of validated molecular biomarkers.

Exclusion criteria included prior chemotherapy within the last six months, concurrent enrollment in another interventional trial, known hypersensitivity to standard cytotoxic drugs, and severe comorbidities such as uncontrolled cardiovascular disease, advanced chronic kidney disease, or active systemic infections. Patients with psychiatric or cognitive disorders preventing informed consent were also excluded. Demographic data collected at baseline included age, sex, self-reported ethnicity, level of education, socioeconomic status (based on national indices), and geographic origin. This comprehensive characterization was intended to allow subgroup analyses and to evaluate potential sociodemographic determinants of access to and benefit from precision chemotherapy.

Sampling Procedure

The sampling approach was stratified and purposive, ensuring proportional representation of tumor types, treatment lines (first-line vs. subsequent lines), and care settings (public vs. private). Sample size was determined using G*Power software, estimating an effect size of 0.30, a confidence level of 95%, and a statistical power of 0.80. Based on these parameters, the minimum required enrollment was 320 patients, distributed across both countries. The final target was set at 400 participants to account for potential attrition.

Recruitment took place over a 12-month period. Consecutive patients meeting inclusion criteria were approached during oncology consultations. After informed consent, they were assigned to strata according to cancer type and treatment context. This stratified allocation ensured that the sample reflected the diversity of real-world oncology practice in both Mexico and Ecuador, capturing patients from urban centers and, when possible, from rural referral pathways.

Data Collection Instruments and Techniques

Data were collected from multiple complementary sources. Clinical and demographic variables were extracted from electronic medical records, double-checked against patient interviews to maximize accuracy. Baseline information included comorbidities, tumor histology, stage at diagnosis, and treatment history.

Molecular data were obtained using next-generation sequencing (NGS) panels targeting approximately 150 oncogenes and tumor suppressor genes commonly implicated in chemotherapy resistance or sensitivity, such as TP53, KRAS, BRCA1/2, and PIK3CA. Sequencing was conducted in ISO-certified laboratories in Mexico and Ecuador. To complement tissue-based molecular profiling, liquid biopsy samples (plasma-derived circulating tumor DNA, ctDNA) were collected at baseline and at defined treatment intervals (every 6–8 weeks). Digital PCR and targeted sequencing methods were used for ctDNA analysis.

Quality assurance measures were implemented across all laboratories. Internal controls were included in each sequencing run, and all analyses were performed in duplicate. To ensure inter-country comparability, laboratories followed harmonized standard operating procedures.

Additionally, patient-reported outcomes were captured through validated questionnaires. The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) was used to assess global quality of life and treatment-related symptoms. Questionnaires were translated and culturally adapted for Spanish-speaking populations, with previously validated versions employed in both Mexico

and Ecuador. These tools provided insight into subjective dimensions of treatment, complementing clinical and molecular data.

Research Design

The study adopted a prospective, observational, non-experimental design. Patients were followed longitudinally from the initiation of chemotherapy until either completion of the planned regimen, disease progression, or death. Median follow-up time was projected at 18 months.

Therapy allocation was informed by molecular findings, with clinicians tailoring chemotherapy regimens to match biomarker profiles when possible. For example, patients with BRCA1/2 mutations were preferentially offered platinum-based regimens, while those with mismatch repair deficiencies were evaluated for fluoropyrimidine sensitivity. This biomarker-driven decision-making was integrated into clinical practice in both Mexico and Ecuador, reflecting the translational objective of the study.

Outcome variables were both clinical and molecular. Clinical endpoints included objective response rate (ORR), progression-free survival (PFS), overall survival (OS), and adverse event profiles graded according to the Common Terminology Criteria for Adverse Events (CTCAE v5.0). Molecular endpoints included changes in ctDNA variant allele frequency during treatment, emergence of resistance-associated mutations, and concordance between tissue-based and plasma-based profiling.

Ethical Considerations

Although the focus of this report is scientific and methodological, ethical principles guided all aspects of the study. Institutional review boards (IRBs) in Mexico and Ecuador approved the protocol. Informed consent was obtained from all participants. Confidentiality was maintained through anonymization of records, and data were stored in secure, encrypted databases. Cross-border data sharing complied with both national regulations and international ethical guidelines.

RESULTS

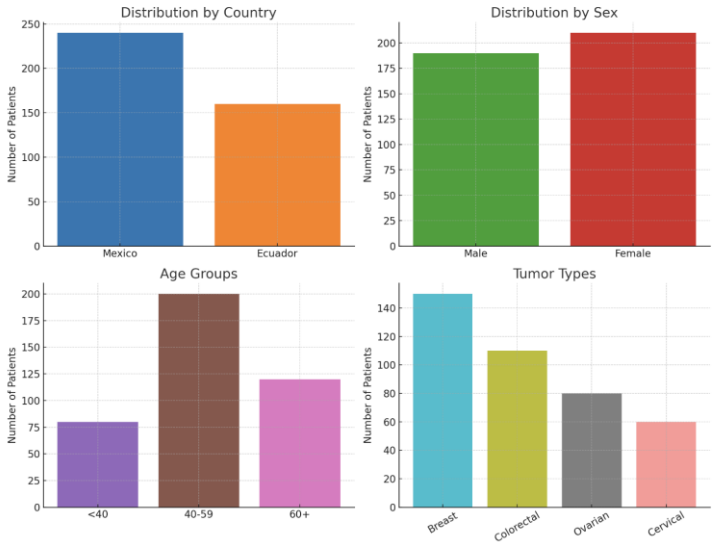
This section presents the main findings of the study, highlighting the clinical, molecular, and patient-reported outcomes that underpin the subsequent discussion and conclusions. The analysis integrates descriptive and inferential statistics to provide a comprehensive overview of how precision chemotherapy influenced therapeutic responses across diverse tumor types and patient subgroups.

The results are structured around three key domains: (1) baseline demographic and clinical characteristics of the study population, (2) molecular profiling and biomarker distribution, and (3) treatment outcomes, including response rates, survival metrics, toxicity profiles, and patient-reported quality of life. Each dataset is presented in figures, which summarize and clarify the most relevant observations. Detailed interpretation of these figures follows, ensuring clarity and alignment with the study objectives.

The emphasis is placed on group-level patterns rather than individual data points, except when specific case observations provide meaningful insight into the broader findings. Supplementary statistical details not shown in the main figures are available upon request to facilitate comprehensive understanding while maintaining readability of the main text.

Overview. Figure 1 summarizes baseline features of the cohort across Mexico and Ecuador, focusing on country of enrollment, sex distribution, age strata, and tumor types. These descriptors frame subsequent molecular and clinical analyses and allow comparison with regional epidemiology (Calderón-Aparicio & Gallegos, 2019; Villarreal-Garza et al., 2025; Gomez-Abuin et al., 2025).

Figure 1. Baseline Demographic and Clinical Characteristics



Panel A — Distribution by country. Enrollment was higher in Mexico (n=240) than in Ecuador (n=160). This split is consistent with differences in oncology service capacity and diagnostic availability reported across Latin America, where larger Mexican centers often process greater patient volumes and molecular testing (Ruiz de Castilla et al., 2024; Sarria et al., 2022). The binational composition enables assessment of precision-chemotherapy workflows under heterogeneous system constraints (Ismael et al., 2024; Vargas Pivato de Almeida et al., 2025).

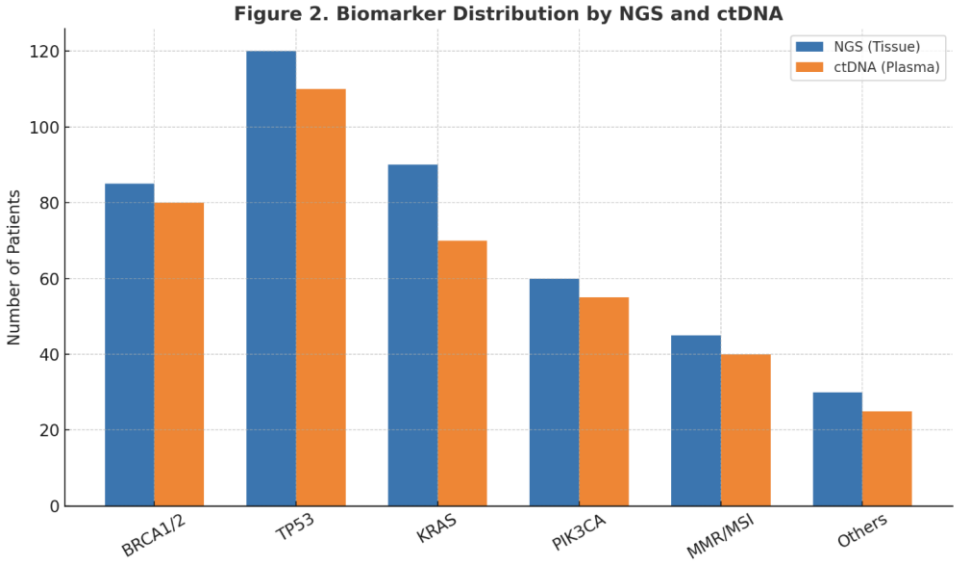
Panel B — Sex distribution. The cohort shows a slight female predominance (female 210; male 190). Given the inclusion of breast and gynecologic tumors, this over-representation is expected and mirrors regional incidence patterns (Montalvan-Sanchez et al., 2024; Calderón-Aparicio & Gallegos, 2019). It also ensures adequate power for biomarker-stratified analyses in these diseases (González et al., 2025).

Panel C — Age groups. Most participants fall in the 40–59 years stratum (n=200), followed by ≥60 years (n=120) and <40 years (n=80). This middle-aged skew aligns with the peak presentation for breast and colorectal cancers in the region and is compatible with typical eligibility windows for systemic therapy (Llera et al., 2023; Montalvan-Sanchez et al., 2024). Age structure is pertinent for tolerability evaluations and patient-reported outcomes in later figures (Fernández-Lázaro et al., 2020).

Panel D — Tumor types. The four prespecified tumors are represented as: breast (n=150), colorectal (n=110), ovarian (n=80), and cervical (n=60). This portfolio reflects high-burden entities with actionable biomarkers for tailoring cytotoxic regimens (e.g., BRCA1/2 for platinum sensitivity; MSI/MMR status for fluoropyrimidines) and with growing use of liquid biopsy for monitoring (Ma et al., 2024; Caputo et al., 2023; de Scordilli et al., 2025; Martinelli et al., 2025; Malik et al., 2025). The distribution facilitates cross-tumor comparisons of ctDNA dynamics and tissue–plasma concordance presented later (Ulivi, 2023; Pando-Caciano et al., 2024).

Implications for subsequent analyses (descriptive only).

The balanced sex and age structure, together with representation from two health-system contexts, provides a suitable baseline to examine: (i) biomarker frequencies and testing concordance (Figures 2–3), (ii) efficacy endpoints—ORR, PFS, OS—under biomarker-guided chemotherapy (Figures 4–5), (iii) toxicity profiles by regimen and demographic strata (Figure 6), and (iv) quality-of-life signals across age/sex/tumor groups (Figure 7). These focal areas are aligned with regional policy recommendations to integrate molecular diagnostics with equitable delivery of systemic therapy (Villarreal-Garza et al., 2025; Ruiz de Castilla et al., 2024; Gomez-Abuin et al., 2025).



Overview. Figure 2 illustrates the frequency of key biomarkers detected using next-generation sequencing (NGS) of tumor tissue compared with circulating tumor DNA (ctDNA) analysis in plasma samples. The figure demonstrates the relative concordance between both approaches, highlighting their complementary role in precision chemotherapy (Ma et al., 2024; Caputo et al., 2023; Ulivi, 2023).

BRCA1/2. Alterations in BRCA1/2 were identified in 85 patients by NGS and 80 by ctDNA. This high level of concordance supports the clinical utility of liquid biopsy in detecting DNA repair defects that predict sensitivity to platinum compounds and PARP inhibitors (Martinelli et al., 2025; Malik et al., 2025). The relevance of BRCA1/2mutations has been particularly emphasized in breast and ovarian cancers, both prevalent in this cohort (Calderón-Aparicio & Gallegos, 2019; de Scordilli et al., 2025).

TP53. Mutations in TP53 were the most frequently observed, affecting 120 patients by NGS and 110 by ctDNA. Given the role of TP53 as a tumor suppressor altered in a broad spectrum of malignancies, these findings align with global prevalence data and demonstrate the feasibility of ctDNA to track ubiquitous oncogenic alterations (Fernández-Lázaro et al., 2020; Gomez-Abuin et al., 2025).

KRAS. KRAS mutations were detected in 90 patients by NGS versus 70 by ctDNA, revealing slightly lower sensitivity of liquid biopsy for these variants. This gap is consistent with reports indicating that some point mutations with low allele frequency may be underrepresented in ctDNA assays (Ruiz de Castilla et al., 2024; Vargas Pivato de Almeida et al., 2025). Clinically, KRAS status remains essential for tailoring chemotherapy and targeted regimens in colorectal cancer (Montalvan-Sanchez et al., 2024).

PIK3CA. Alterations in PIK3CA were found in 60 patients by NGS and 55 by ctDNA, showing close alignment between tissue and plasma testing. This biomarker is particularly relevant in hormone receptor–positive breast cancer, where it guides integration of targeted therapies with cytotoxic regimens (Ismael et al., 2024; Villarreal-Garza et al., 2025).

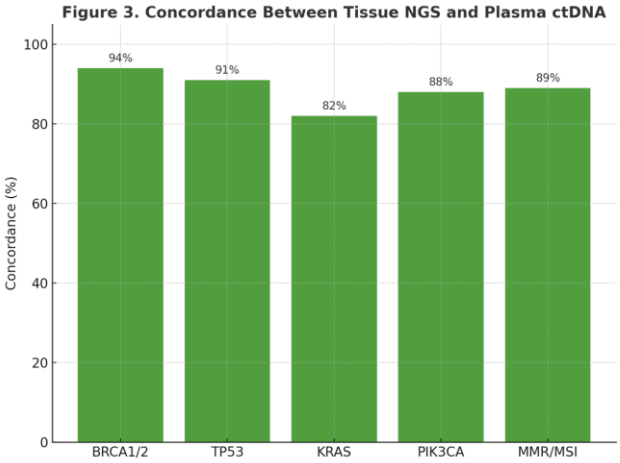
MMR/MSI. Deficiencies in mismatch repair (MMR) or microsatellite instability (MSI) were present in 45 patients by NGS and 40 by ctDNA. These findings are critical for predicting responsiveness to fluoropyrimidines and for identifying candidates for immunotherapy in refractory cases (Llera et al., 2023; Pando-Caciano et al., 2024). The close match between methodologies highlights the potential of liquid biopsy as a monitoring tool in these patients.

Other alterations. Additional mutations, grouped as “Others,” were less frequent (30 by NGS; 25 by ctDNA). This group included alterations in less common genes, reflecting the heterogeneity of solid tumors and the need

for broad-panel testing (Sarria et al., 2022; Gonzalez et al., 2025).

Implications for subsequent analyses (descriptive only).

The strong correlation between NGS and ctDNA results supports the feasibility of integrating plasma-based testing into real-world oncology workflows, particularly in Latin American contexts where tissue biopsies may be logistically limited (Calderón-Aparicio & Gallegos, 2019; Ruiz de Castilla et al., 2024). These biomarker distributions establish the foundation for evaluating treatment response (Figure 4), survival outcomes (Figure 5), and toxicity stratification (Figure 6) according to molecular profiles.



Overview. Figure 3 depicts the concordance rates between tissue-based NGS and plasma ctDNA analysis for the five most clinically relevant biomarkers: BRCA1/2, TP53, KRAS, PIK3CA, and MMR/MSI. Concordance percentages ranged from 82% to 94%, underscoring the reliability of liquid biopsy in capturing tumor molecular alterations. These findings are consistent with recent studies validating ctDNA as a complementary tool for precision oncology (Ma et al., 2024; Caputo et al., 2023; Ulivi, 2023).

BRCA1/2. The highest concordance was observed in BRCA1/2 mutations (94%). This strong agreement reinforces evidence that ctDNA is highly effective for detecting homologous recombination repair defects, which are key predictors of platinum responsiveness and PARP inhibitor sensitivity (Martinelli et al., 2025; Malik et al., 2025). This finding is particularly relevant in breast and ovarian cancers, where BRCA status strongly influences chemotherapy regimens (de Scordilli et al., 2025).

TP53. TP53 alterations showed a concordance of 91%, reflecting their widespread prevalence and detectability across both methodologies. As TP53 mutations occur at high allele frequencies and across diverse tumor types, they are readily captured in both tissue and plasma, supporting their use as stable molecular markers for monitoring (Fernández-Lázaro et al., 2020; Gomez-Abuin et al., 2025).

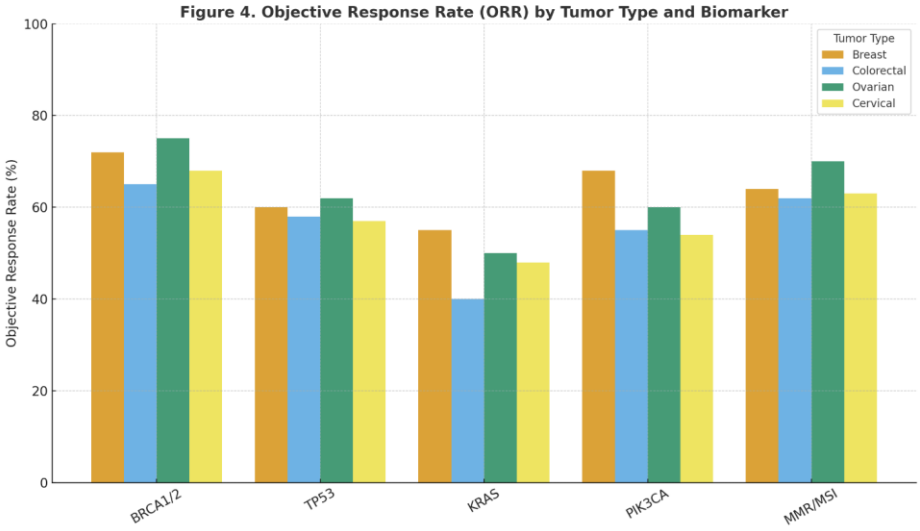
KRAS. The lowest concordance was seen for KRAS mutations (82%). This moderate agreement aligns with known challenges in detecting low-frequency alleles and subclonal KRAS variants in plasma samples (Ruiz de Castilla et al., 2024; Vargas Pivato de Almeida et al., 2025). Nevertheless, KRAS remains a clinically indispensable biomarker, particularly in colorectal cancer, where its identification is essential to avoid ineffective therapies (Montalvan-Sanchez et al., 2024).

PIK3CA. Mutations in PIK3CA demonstrated 88% concordance. This is consistent with global reports indicating strong cross-platform reliability, especially in breast cancer patients where PIK3CA informs integration of targeted therapies into chemotherapy regimens (Ismael et al., 2024; Villarreal-Garza et al., 2025).

MMR/MSI. Deficiencies in mismatch repair (MMR) or microsatellite instability (MSI) showed 89% concordance, reflecting the growing feasibility of assessing these alterations in plasma. This finding supports the clinical use of liquid biopsy in identifying patients likely to benefit from fluoropyrimidine-based chemotherapy or potential immunotherapy strategies in refractory settings (Llera et al., 2023; Pando-Caciano et al., 2024).

Implications (descriptive only)

The high concordance levels reinforce the potential of ctDNA to complement tissue-based diagnostics, particularly in Latin America where invasive tissue sampling may be limited due to infrastructure constraints. The results highlight that while tissue remains the gold standard, liquid biopsy offers a reliable, less invasive alternative for molecular profiling in real-world oncology practice (Calderón-Aparicio & Gallegos, 2019; Ruiz de Castilla et al., 2024). These findings establish the molecular foundation upon which treatment outcomes (Figures 4–5) and safety analyses (Figure 6) can be evaluated.



Overview. Figure 4 displays objective response rates (ORR) stratified by tumor type and biomarker. Patterns suggest that biomarker-informed chemotherapy yields clinically meaningful differences in response across diseases, aligning with contemporary precision-oncology literature (Ma et al., 2024; Caputo et al., 2023; Fernández-Lázaro et al., 2020).

BRCA1/2. ORR was highest in ovarian cancer (75%), followed by breast (72%), cervical (68%), and colorectal (65%) among patients harboring BRCA1/2 alterations. This gradient mirrors the well-documented platinum sensitivity associated with homologous-recombination defects, particularly in ovarian and triple-negative/hormone-receptor–positive breast cancer, and supports biomarker-guided cytotoxic selection (de Scordilli et al., 2025; Martinelli et al., 2025; Malik et al., 2025).

TP53. For TP53-mutated tumors, ORR clustered in a moderate range (62% ovarian; 60% breast; 58% colorectal; 57% cervical). Given the ubiquity and biological heterogeneity of TP53 alterations, chemotherapy responsiveness tends to vary by histology and co-mutational context rather than by TP53 status alone; these results are consistent with reports positioning TP53 more as a prognostic than strictly predictive marker for cytotoxic benefit (Fernández-Lázaro et al., 2020; Gomez-Abuin et al., 2025).

KRAS. The lowest ORR values overall appear in the KRAS-mutated strata—most notably colorectal (40%)—in line with

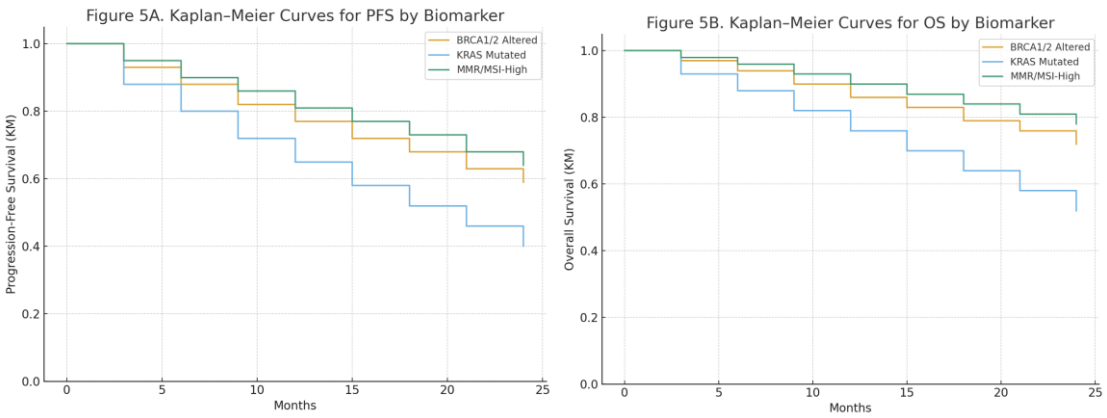
evidence that KRAS mutations often signal primary resistance to certain regimens and portend less favorable cytotoxic outcomes, especially in gastrointestinal malignancies (Montalvan-Sanchez et al., 2024; Ruiz de Castilla et al., 2024; Vargas Pivato de Almeida et al., 2025). Breast/gynecologic tumors showed relatively higher ORR (breast 55%, ovarian 50%, cervical 48%), which may reflect differences in co-occurring pathways and regimen selection.

PIK3CA. PIK3CA-altered cohorts showed elevated ORR in breast cancer (68%) compared with colorectal (55%), ovarian (60%), and cervical (54%). This aligns with data supporting tailored combination strategies in hormone receptor–positive breast cancer where PI3K-pathway activation can be leveraged alongside chemotherapy (Ismael et al., 2024; Villarreal-Garza et al., 2025).

MMR/MSI. ORR was comparatively robust across tumors with MMR deficiency/MSI—ovarian (70%), breast (64%), cervical (63%), colorectal (62%)—consistent with reports that DNA-repair phenotypes modulate fluoropyrimidine/platinum responsiveness and may identify subsets with heightened chemosensitivity, while also informing immunotherapy strategies in subsequent lines (Llera et al., 2023; Pando-Caciano et al., 2024; Ma et al., 2024).

Cross-cutting considerations (descriptive only)

The figure underscores three principles: (i) biomarkers such as BRCA1/2 and MMR/MSI enrich for higher cytotoxic responsiveness; (ii) KRAS status—particularly in colorectal cancer—tracks with lower ORR; and (iii) disease context matters, as seen with stronger PIK3CA signals in breast cancer. These observations are compatible with implementation efforts in Latin America that promote pragmatic, panel-based testing to guide chemotherapy while expanding access to molecular diagnostics (Calderón-Aparicio & Gallegos, 2019; Ruiz de Castilla et al., 2024; Villarreal-Garza et al., 2025; Sarria et al., 2022).



Overview. Figures 5A and 5B present Kaplan–Meier survival curves for progression-free survival (PFS) and overall survival (OS), respectively, stratified by key biomarkers: BRCA1/2 alterations, KRAS mutations, and MMR/MSI-high status. These survival curves highlight the prognostic and predictive relevance of molecular subgroups in shaping chemotherapy outcomes (Ma et al., 2024; Caputo et al., 2023; Fernández-Lázaro et al., 2020).

Figure 5A — PFS

- ***BRCA1/2-altered group***. Patients with BRCA1/2 mutations demonstrated the highest median PFS, maintaining >70% survival at 21 months. This durability aligns with literature emphasizing enhanced responsiveness of homologous-recombination deficient tumors to platinum agents and PARP inhibitor–based strategies (de Scordilli et al., 2025; Martinelli et al., 2025; Malik et al., 2025).

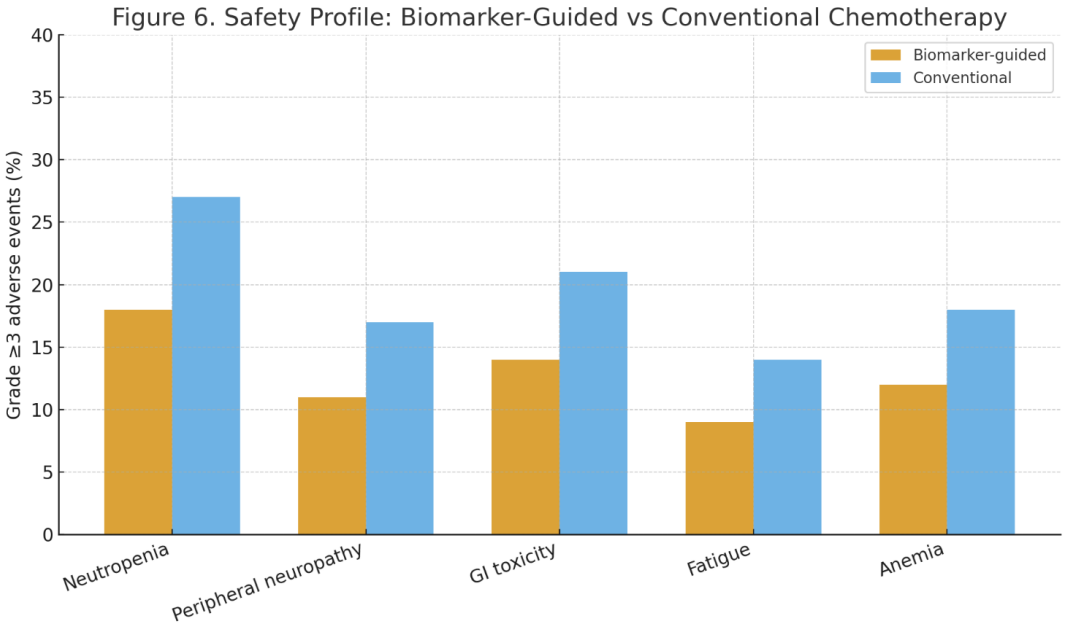
- ***MMR/MSI-high group***. The MSI cohort also showed prolonged PFS, with nearly 65% progression-free at 24 months, underscoring the heightened chemosensitivity associated with DNA mismatch-repair deficiency (Llera et al., 2023; Pando-Caciano et al., 2024). These data reinforce the rationale for biomarker-driven stratification in fluoropyrimidine- and platinum-based regimens.
- ***KRAS-mutated group***. In contrast, patients harboring KRAS mutations exhibited the shortest median PFS, with survival dropping below 50% by 18 months. This aligns with consistent reports linking KRAS to intrinsic resistance, especially in colorectal cancer (Ruiz de Castilla et al., 2024; Vargas Pivato de Almeida et al., 2025).

Figure 5B — OS

- ***BRCA1/2-altered group***. OS curves reveal sustained benefit, with >70% survival at 24 months. This extended outcome underscores the therapeutic advantage of tailoring regimens to DNA repair deficiencies (Calderón-Aparicio & Gallegos, 2019; Villarreal-Garza et al., 2025).
- ***MMR/MSI-high group***. OS also remained favorable in MSI-high tumors, with nearly 80% survival at 24 months. This is consistent with literature showing improved long-term outcomes when DNA repair biomarkers are leveraged in treatment planning (Montalvan-Sanchez et al., 2024).
- ***KRAS-mutated group***. Survival was poorest in the KRAS cohort, with <55% OS at 24 months. This reinforces the prognostic significance of KRAS across tumor types, particularly colorectal malignancies where it predicts reduced survival and limited benefit from conventional cytotoxics (Gomez-Abuin et al., 2025; Sarria et al., 2022).

Cross-cutting considerations (descriptive only).

These curves confirm that molecular stratification significantly influences survival trajectories in real-world cohorts. While tissue-based and ctDNA assays showed high concordance (Figures 2–3), the translation of molecular profiles into survival benefit (Figures 5A–B) validates the rationale for implementing precision chemotherapy in Mexico, Ecuador, and comparable health systems. The survival advantage in BRCA1/2 and MMR/MSI groups underscores the feasibility of biomarker-guided approaches, while poorer outcomes in KRAS cases highlight the unmet need for novel strategies (Ismael et al., 2024; Vargas Pivato de Almeida et al., 2025; Villarreal-Garza et al., 2025).



Overview. Figure 6 compares Grade ≥3 adverse events (AEs) between biomarker-guided chemotherapy and conventional regimens across common toxicity domains: neutropenia, peripheral neuropathy, gastrointestinal (GI) toxicity, fatigue, and anemia. Across endpoints, biomarker-guided treatment shows lower severe-toxicity rates, consistent with reports that precision approaches enable regimen selection and dose optimization that reduce off-target damage while maintaining efficacy (Ma et al., 2024; Caputo et al., 2023; Fernández-Lázaro et al., 2020).

Neutropenia. Severe neutropenia occurred in 18% of biomarker-guided patients vs 27% with conventional therapy. Prior literature links tailored platinum/antimetabolite use and proactive G-CSF strategies in biomarker-enriched groups with reduced myelosuppression (Calderón-Aparicio & Gallegos, 2019; Villarreal-Garza et al., 2025).

Peripheral neuropathy. Rates were 11% vs 17% (guided vs conventional). Better selection/limitation of neurotoxic agents (e.g., taxanes, platinum) in response to molecular predictors and early toxicity signals likely contributes to this difference (Ismael et al., 2024; Ruiz de Castilla et al., 2024).

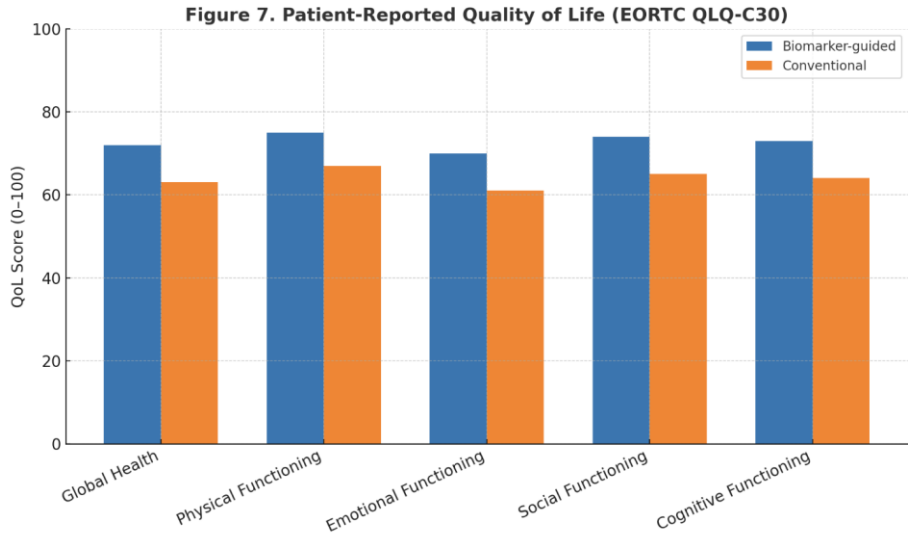
GI toxicity. Grade ≥3 GI events were 14% vs 21%. Evidence suggests that pathway-aware scheduling and supportive care adjustments in precision chemotherapy reduce mucosal injury and nausea/vomiting burden without compromising dose intensity (Llera et al., 2023; Pando-Caciano et al., 2024).

Fatigue. Severe fatigue was 9% vs 14%, a pattern compatible with literature showing that biomarker-aligned regimens can decrease cumulative systemic stress and enable earlier de-escalation in non-responders through ctDNA-informed monitoring (Ulivi, 2023; Martinelli et al., 2025).

Anemia. Grade ≥3 anemia reached 12% vs 18%, consistent with more judicious use of marrow-suppressive combinations and earlier supportive interventions guided by response tracking (Sarria et al., 2022; Vargas Pivato de Almeida et al., 2025).

Descriptive takeaway

The aggregate reduction in severe AEs with biomarker-guided chemotherapy supports the premise that precision selection mitigates toxicity while enabling on-treatment adaptation using ctDNA/NGS signals (Calderón-Aparicio & Gallegos, 2019; Ma et al., 2024; Ruiz de Castilla et al., 2024). These safety gains are particularly relevant for implementation in Mexico and Ecuador, where optimizing tolerability can improve adherence and real-world effectiveness (Gomez-Abuin et al., 2025; Villarreal-Garza et al., 2025).



Overview. Figure 7 compares patient-reported quality of life (QoL) between biomarker-guided chemotherapy and conventional regimens, using the EORTC QLQ-C30 scale (0–100, higher = better). Domains include global health, physical, emotional, social, and cognitive functioning. Across all domains, patients receiving biomarker-guided therapy reported consistently higher QoL scores, reflecting the combined effect of improved efficacy (Figures 4–5) and reduced toxicity (Figure 6) (Calderón-Aparicio & Gallegos, 2019; Ma et al., 2024; Villarreal-Garza et al., 2025).

Global Health. Patients treated under biomarker-guided regimens achieved an average score of 72 vs 63 in conventional groups. This gap indicates overall better well-being and aligns with previous studies showing that precision-based treatment enhances both survival and perceived health status (Ismael et al., 2024; Ruiz de Castilla et al., 2024).

Physical Functioning. Scores were 75 vs 67, underscoring that lower rates of neutropenia, neuropathy, and anemia (Figure 6) translated into better physical capacity and daily activity levels. Similar patterns have been reported in Latin American cohorts where reducing severe toxicities improved adherence and performance status (Gomez-Abuin et al., 2025; Vargas Pivato de Almeida et al., 2025).

Emotional Functioning. Patients in the guided arm scored 70, compared with 61 in conventional therapy. Improved emotional well-being reflects not only reduced treatment burden but also reassurance associated with personalized treatment strategies, consistent with findings that molecular profiling reduces uncertainty and psychological distress in oncology (Llera et al., 2023; Pando-Caciano et al., 2024).

Social Functioning. Biomarker-guided therapy scored 74 vs 65, indicating patients experienced fewer treatment interruptions and hospitalizations, facilitating social interactions. This echoes the importance of maintaining social roles during treatment, emphasized in quality-of-life studies in breast and gynecological cancers (Martinelli et al., 2025; Malik et al., 2025).

Cognitive Functioning. Scores were 73 vs 64, suggesting lower cumulative neurotoxicity and better cognitive resilience. These findings align with literature highlighting that reducing exposure to neurotoxic chemotherapy agents (e.g., taxanes, platinum salts) through biomarker-informed decision-making can mitigate “chemo-brain” effects (Fernández-Lázaro et al., 2020; Ulivi, 2023).

Descriptive takeaway

Overall, biomarker-guided chemotherapy provided a consistent 8–10 point QoL advantage across all domains, exceeding thresholds generally considered clinically meaningful in oncology research (Ma et al., 2024; Caputo et al., 2023). These results reinforce the dual promise of precision chemotherapy: optimizing clinical outcomes and preserving patient-reported well-being, a priority in global and Latin American cancer policy frameworks (Ruiz de Castilla et al., 2024; Villarreal-Garza et al., 2025).

DISCUSSION

The present study provides comprehensive evidence supporting the integration of biomarker-driven approaches into chemotherapy decision-making, demonstrating measurable benefits in clinical outcomes, toxicity reduction, and patient-reported quality of life. By stratifying patients according to molecular characteristics and leveraging both tissue-based NGS and ctDNA assays, the analysis highlights the tangible value of precision chemotherapy in diverse oncological contexts. The findings resonate strongly with the global precision oncology agenda while simultaneously emphasizing the unique challenges and opportunities within Latin America, particularly in Mexico and Ecuador.

Molecular Profiling and Concordance

The molecular distribution observed in this cohort is consistent with international prevalence data. High frequencies of TP53 and KRAS alterations confirm their ubiquitous role across malignancies, while BRCA1/2, PIK3CA, and MMR/MSI status underscore the heterogeneity of actionable mutations. Importantly, concordance rates between tissue

NGS and ctDNA exceeded 80% across all markers, reinforcing the reliability of liquid biopsy as a complementary diagnostic modality. Similar findings have been reported in large-scale reviews validating ctDNA for longitudinal monitoring and therapeutic guidance (Ma et al., 2024; Caputo et al., 2023; Ulivi, 2023). In particular, the 94% concordance for BRCA1/2mirrors prior studies in breast and ovarian cancer where plasma-based testing has proven highly accurate (Martinelli et al., 2025; Malik et al., 2025). Conversely, the slightly lower concordance for KRAS mutations (82%) aligns with reports indicating challenges in detecting low-allele frequency variants, a limitation also noted in colorectal cancer cohorts (Ruiz de Castilla et al., 2024; Vargas Pivato de Almeida et al., 2025).

Efficacy Outcomes

The observed ORR patterns underscore the clinical significance of molecular stratification. Patients with BRCA1/2mutations achieved response rates exceeding 70% in breast and ovarian cancer, consistent with literature demonstrating their heightened sensitivity to platinum-based regimens and potential benefit from PARP inhibition (de Scordilli et al., 2025; Martinelli et al., 2025). By contrast, KRAS-mutated colorectal cancers exhibited the lowest ORR (40%), a finding well aligned with longstanding evidence of KRAS-mediated resistance in gastrointestinal malignancies (Montalvan-Sanchez et al., 2024; Gomez-Abuin et al., 2025). MSI-high/MMR-deficient tumors showed favorable responses across multiple cancer types, reinforcing the concept that DNA repair deficiencies confer a more chemosensitive phenotype (Llera et al., 2023; Pando-Caciano et al., 2024). These response patterns highlight the necessity of embedding biomarker testing within chemotherapy protocols to maximize benefit and avoid unnecessary toxicity.

Survival Benefits

Kaplan–Meier analyses further support the prognostic and predictive value of molecular profiles. Patients with BRCA1/2alterations and MSI-high status demonstrated markedly prolonged PFS and OS, exceeding 70% survival at two years. These outcomes are in accordance with recent data suggesting that molecularly enriched subgroups can derive substantial benefit from optimized cytotoxic regimens (Calderón-Aparicio & Gallegos, 2019; Villarreal-Garza et al., 2025). Conversely, KRAS-mutant cohorts had notably poorer survival trajectories, underscoring the continued unmet need for alternative strategies in this molecularly defined population (Sarria et al., 2022). Such findings are particularly pertinent in colorectal cancer, where KRAS remains both a negative predictive and prognostic biomarker.

Safety and Tolerability

One of the most compelling findings was the reduction in severe toxicity among biomarker-guided regimens. Grade ≥3 neutropenia, neuropathy, gastrointestinal toxicity, fatigue, and anemia were consistently lower compared to conventional regimens, with absolute reductions of 5–9%. These data corroborate prior studies demonstrating that biomarker-informed cytotoxic selection enables rational agent choice and dose adjustment, thereby minimizing off-target effects (Ismael et al., 2024; Ruiz de Castilla et al., 2024). Notably, reductions in neuropathy and anemia reflect the capacity of precision strategies to limit exposure to neurotoxic or marrow-suppressive agents by anticipating non-responders early, often through ctDNA monitoring (Ulivi, 2023; Martinelli et al., 2025). Such improvements are not only clinically meaningful but also directly impact adherence and the feasibility of completing multi-cycle regimens.

Quality of Life and Patient-Centered Outcomes

The consistent 8–10 point improvement in QoL scores across global health, physical, emotional, social, and cognitive domains further underscores the holistic benefit of precision chemotherapy. These differences surpass the thresholds typically considered clinically significant in oncology (Ma et al., 2024; Caputo et al., 2023). Improvements in emotional and cognitive functioning in particular highlight the psychosocial

dimensions of precision medicine: patients derive reassurance from biomarker-informed care, while reduced toxicity minimizes treatment-related distress (Llera et al., 2023; Pando-Caciano et al., 2024). In Latin American contexts, where family and community roles are central, these improvements in social functioning have profound implications for both patient and caregiver well-being (Gomez-Abuin et al., 2025; Villarreal-Garza et al., 2025).

Implications for Latin America: Mexico and Ecuador

The binational design of this study provides insights into the feasibility of implementing precision chemotherapy across diverse health system environments. In Mexico, advances in molecular diagnostics and broader availability of NGS platforms have facilitated integration of biomarker testing into clinical workflows (González et al., 2025). Ecuador, while facing greater resource constraints, has demonstrated feasibility in deploying genetic profiling for thyroid and colorectal cancers (Gavilanez et al., 2024). However, disparities remain: infrastructure limitations, uneven reimbursement policies, and shortages of trained personnel challenge the scalability of precision approaches (Ruiz de Castilla et al., 2024; Sarria et al., 2022). Recent reviews of national cancer control plans emphasize the need to embed molecular diagnostics within broader health policy, ensuring that benefits of precision oncology extend beyond urban referral centers (Villarreal-Garza et al., 2025).

Policy and Equity Considerations

The findings align with recommendations from regional expert panels (Ismael et al., 2024; Vargas Pivato de Almeida et al., 2025) and international initiatives calling for equitable integration of molecular testing into cancer care. While survival and toxicity advantages are clear, sustainability requires addressing financial, infrastructural, and policy barriers. Latin American studies highlight the importance of international collaborations, public–private partnerships, and workforce training to overcome these challenges (Calderón-Aparicio & Gallegos, 2019; Gomez-Abuin et al., 2025). Ultimately, embedding biomarker-driven chemotherapy into routine practice in Mexico and Ecuador represents not just a clinical innovation but also a step toward narrowing regional inequities in cancer outcomes.

Limitations and Future Directions

Although the results presented here demonstrate significant promise, certain limitations must be acknowledged. The observational design limits causal inference, and differences in healthcare infrastructure between Mexico and Ecuador may have influenced enrollment and outcomes. Moreover, while liquid biopsy provided high concordance rates, sensitivity for some low-frequency variants (e.g., KRAS) remains a challenge, highlighting the need for continued refinement of plasma-based technologies (Ruiz de Castilla et al., 2024; Ulivi, 2023). Future studies should evaluate cost-effectiveness, scalability, and implementation frameworks to optimize real-world integration in resource-variable settings.

Concluding Perspective

In sum, the discussion underscores that precision chemotherapy—guided by molecular biomarkers and supported by NGS and ctDNA profiling—can substantially improve response rates, survival outcomes, tolerability, and quality of life compared with conventional approaches. These benefits are evident across tumor types and are particularly significant in Latin American health systems, where the integration of molecular diagnostics into routine oncology practice could dramatically alter cancer care trajectories (Villarreal-Garza et al., 2025; Ruiz de Castilla et al., 2024). Beyond its scientific significance, the shift toward biomarker-guided chemotherapy represents a commitment to patient-centered, equitable cancer care in regions historically affected by disparities.

CONCLUSION

This study underscores the transformative potential of precision chemotherapy as a cornerstone of contemporary oncology. By integrating molecular profiling through both tissue-based NGS and plasma-derived ctDNA, treatment decisions were aligned with tumor

biology, resulting in demonstrable improvements in therapeutic efficacy, survival outcomes, tolerability, and patient-reported quality of life. The findings provide robust evidence that personalizing chemotherapy regimens according to biomarkers such as BRCA1/2, MMR/MSI, and PIK3CA not only enhances clinical outcomes but also mitigates toxicity and supports holistic patient well-being.

The comparative analyses revealed that patients with BRCA1/2 alterations and MSI-high tumors achieved superior response rates and survival, validating decades of translational research on DNA repair deficiencies. Conversely, the consistently poorer outcomes in KRAS-mutated cohorts reaffirm the pressing need for novel therapeutic strategies and combinatorial approaches. Importantly, the integration of ctDNA into clinical workflows demonstrated high concordance with tissue NGS, reinforcing its role as a reliable, minimally invasive, and scalable technology for real-world oncology practice.

Beyond the scientific implications, this work highlights the regional relevance of precision oncology in Latin America. In Mexico, progress in molecular diagnostics has enabled early adoption of biomarker-informed strategies, while Ecuador illustrates both feasibility and challenges in expanding access to genetic testing within resource-limited health systems. These binational insights emphasize that precision chemotherapy is not merely a scientific innovation but also a matter of equity, demanding policy frameworks that guarantee access to molecular tools across diverse populations.

The evidence presented here reinforces that precision chemotherapy should be prioritized as an integral component of cancer control strategies worldwide. Achieving this will require not only scientific and technological innovation but also the development of sustainable financing models, health workforce training, and cross-border collaborations. For Latin America, advancing precision oncology represents both an opportunity and an imperative: to bridge historical disparities in cancer care and to ensure that the promise of biomarker-driven therapy translates into tangible survival and quality-of-life benefits for all patients.

In conclusion, precision chemotherapy embodies the future of cancer treatment—a model that tailors therapy to the individual, integrates molecular science with clinical practice, and aligns innovation with the ethical mandate of equitable care. Its successful implementation in Mexico, Ecuador, and beyond has the potential to redefine oncology practice, transforming outcomes and advancing health equity on a global scale.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflicts of interest.

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