Real-World Del(17p), TP53, and IGHV Baseline Testing Patterns in Chronic Lymphocytic Leukemia (CLL) Within a Large Network of US Community Oncology Practices

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Background and Objectives

- Biomarker testing is essential for evidence-based CLL management, and guidelines recommend assessing del(17p), TP53, and IGHV to inform prognosis and treatment.
- Incomplete or delayed testing may lead to suboptimal treatment decisions, particularly with the expanding availability of targeted therapies.
- Historically, real-world studies, including the informCLL registry, have shown inconsistent adoption of comprehensive biomarker testing, with TP53 and IGHV assessed in only a minority of patients (≈10–30%), especially in community practice where most care is delivered.
- Understanding real-world testing patterns can identify gaps in guideline implementation and inform strategies to improve equitable, high-quality CLL care in community oncology settings.

Objective:
To evaluate real-world biomarker testing rates for CLL across a large network of US community practices.

Study Design and Methodology

Study Design: Retrospective observational cohort study

Data Source: structured & human-review curated unstructured electronic medical record (EMR) data from practices affiliated with ONCare Alliance, a national network of 31 community oncology practices that represents more than 3 million patients

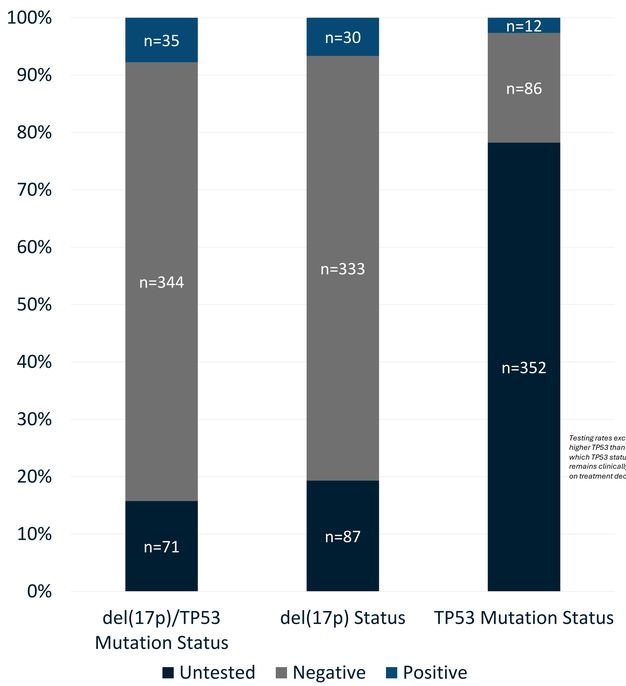
Study Population: 450 adults diagnosed with CLL and initiating frontline therapy between 1/1/2022 and 6/30/2024 within ONCare Alliance; patients were randomly screened for inclusion.

Statistical Methods

- Patient characteristics were summarized descriptively overall and by biomarker status.
- Biomarker testing patterns from initial CLL diagnosis through 30 days after the start of frontline therapy were assessed descriptively.
- Logistic regression identified baseline demographic and clinical characteristics as predictors of receipt of del(17p) or TP53 testing. Variables were selected based on 0.1 criteria of entry and stay.

Results

Figure 1. del(17p) and TP53 Testing and Mutation Status



Testing rates exceeded prior real-world reports, though uptake varied by biomarker, with higher TP53 than IGHV testing. This pattern may reflect contemporary CLL practice, in which TP53 status directly informs frontline treatment selection, whereas IGHV status remains clinically relevant as a prognostic factor but may have less immediate impact on treatment decisions.

Table 1. del(17p) by TP53 Testing and Mutation Status

Number (%) of Patients		TP53 Status		
		Negative	Positive	Untested
del(17p) Status	Negative	70 (15.6)	4 (0.9)	259 (57.6)
	Positive	1 (0.2)	7 (1.6)	22 (4.9)
	Untested	15 (3.3)	1 (0.2)	71 (15.8)

Figure 2. IGHV Testing and Mutation Status

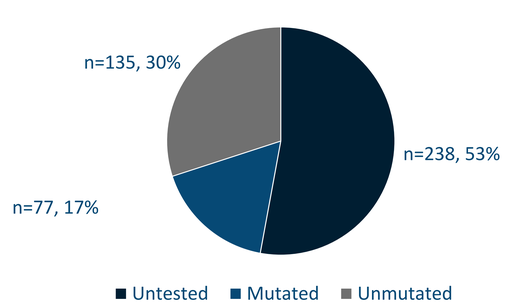


Table 2. Patient Characteristics by del(17p)/TP53 and IGHV Testing and Mutation Status

	Overall (N=450)	del(17p)/TP53				IGHV			
		Untested (N=71)	Negative (N=344)	Positive (N=35)	p-Value	Untested (N=71)	Mutated (N=77)	Unmutated (N=135)	p-Value
Mean (SD) Age at Index (in Years)	70.5 (10.6)	74.3 (9.8)	69.4 (10.7)	73.3 (9.5)	**0.0003**	71.2 (10.7)	68.7 (11.4)	70.1 (10.0)	0.1585
Female Sex, n (%)	160 (35.6)	33 (46.5)	111 (32.3)	16 (45.7)	**0.0318**	91 (38.2)	27 (35.1)	42 (31.1)	0.3833
Race									
White	400 (88.9)	63 (88.7)	305 (88.7)	32 (91.4)	0.7140	214 (89.9)	70 (90.9)	116 (85.9)	0.4480
Black/African American	24 (5.3)	2 (2.8)	20 (5.8)	2 (5.7)		9 (3.8)	4 (5.2)	11 (8.1)	
Other/Undocumented	26 (5.8)	6 (8.5)	19 (5.5)	1 (2.9)		15 (6.3)	3 (3.9)	8 (5.9)	
Hispanic/Latino Ethnicity, n (%)	13 (2.9)	3 (4.2)	8 (2.3)	2 (5.7)	0.1520	9 (3.8)	2 (2.6)	2 (1.5)	0.2270
Risk Classification, n (%)									
Low	65 (14.4)	3 (4.2)	60 (17.4)	2 (5.7)		34 (14.3)	14 (18.2)	17 (12.6)	
Intermediate	49 (10.9)	1 (1.4)	48 (14.0)	0 (0.0)	**<0.0001**	26 (10.9)	8 (10.4)	15 (11.1)	**0.0047**
High	34 (7.6)	0 (0.0)	23 (6.7)	11 (31.4)		10 (4.2)	3 (3.9)	21 (15.6)	
Other/Undocumented	302 (67.1)	67 (94.4)	213 (61.9)	22 (62.9)		168 (70.6)	52 (67.5)	82 (60.7)	
Any Comorbidity, n (%)	343 (76.2)	61 (85.9)	253 (73.5)	29 (82.9)	0.0526	185 (77.7)	51 (66.2)	107 (79.3)	0.0734
ECOG Performance Status, n (%)									
0-1	363 (80.7)	50 (70.4)	282 (82.0)	31 (88.6)	0.1140	191 (80.3)	58 (75.3)	114 (84.4)	**0.0474**
≥2	37 (8.2)	11 (15.5)	24 (7.0)	2 (5.7)		25 (10.5)	4 (5.2)	8 (5.9)	
Undocumented	50 (11.1)	10 (14.1)	38 (11.0)	2 (5.7)		22 (9.2)	15 (19.5)	13 (9.6)	

Abbreviations: ECOG, Eastern Cooperative Oncology Group; SD, standard deviation

Table 3. Patient Characteristics Associated with del(17p)/TP53 Tested Status

Covariates	Estimate	Standard Error	Pr > Chi-Square	Odds Ratio (95% CI)
Age at Index (in Years)	-0.0380	0.0135	**0.0050**	0.963 (0.937, 0.989)
Sex (Female vs. Male)	-0.6608	0.2738	**0.0158**	0.516 (0.302, 0.883)
ECOG Performance Status			**0.0306**[a]	
Impaired (ECOG ≥ 2) vs. Not Impaired (ECOG 0 – 1)	-0.9884	0.4049	**0.0146**	0.372 (0.168, 0.823)
Undocumented vs. Not Impaired (ECOG 0 – 1)	-0.5598	0.3994	0.1610	0.571 (0.261, 1.250)
Hypertension (Yes vs. No)	-0.5881	0.3079	0.0561	0.555 (0.304, 1.015)

Abbreviations: CI, confidence interval; ECOG, Eastern Cooperative Oncology Group
[a] Type III test p-value.

- **Mutation and Testing Status** (**Figure 1-2**, **Table 1**)
  - Of the 450 patients, 379 (84.2%) were tested for del(17p) or TP53; of those tested, 35 (9.2%) were positive and 344 (90.8%) were negative. Most (297/379, 78.4%) had a single test—nearly all for del(17p) (281/297, 94.6%).
  - IGHV testing occurred in 212 patients (47.1%) with 135 unmutated and 77 mutated (63.7% and 36.3% of those tested, respectively).
  - Ten patients (2.2%) were both IGHV-unmutated and del(17p)/TP53-positive.
- **Patient Characteristics (Table 2-3)**
  - Mean age was 70.5 years; 35.6% were female, 88.9% White, and 5.3% Black/African American.
  - Del(17p)/TP53-negative patients were younger and less often female; IGHV groups showed no demographic differences.
  - Stage at diagnosis varied by IGHV (p = 0.0090), with mutated patients more often stage IV (24.7%).
  - High-risk classification was more common among del(17p)/TP53-positive and IGHV-unmutated patients.
  - Overall, 76.2% had ≥1 comorbidity, with nominally lower rates in del(17p)/TP53-negative (73.5%) and IGHV-mutated (66.2%) groups.
  - Testing was predicted by younger age, male sex, and better performance status; presence of hypertension was associated with lower testing rates.

Conclusions

- **Testing rates exceeded prior real-world reports, though uptake varied by biomarker, with higher TP53 than IGHV testing. This pattern may reflect contemporary CLL practice, in which TP53 status directly informs frontline treatment selection, whereas IGHV status remains prognostic and clinically relevant but may have less immediate impact on treatment decisions.**
- **These findings suggest that participation in a coordinated network, supported by provider education, shared clinical pathways, and integrated data platforms, can improve adoption of clinically actionable, guideline-recommended testing in community practice and help narrow historical gaps.**

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