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High-Sensitivity Peripheral Blood Measurable Residual Disease Detection in Acute Myeloid Leukemia Using a Microfluidic Rare-Cell Imaging Immunophenotyping Platform

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INTRODUCTION

MRD assessment in AML is crucial for prognosis and therapeutic decision-making. Current methods have critical limitations:

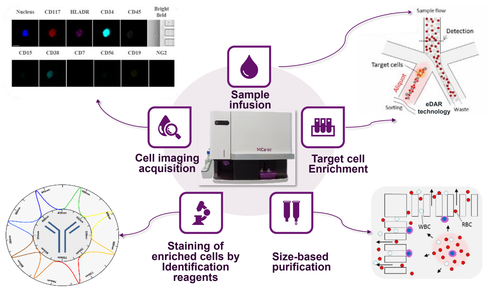
- ▶ **BM-MFC:** Broadly applicable but modest sensitivity (≥0.01%) and sampling variability.
- ▶ **RT-qPCR:** Highly sensitive but restricted to patients with trackable genetic alterations.
- ▶ **Unmet Need:** No sensitive genetic marker-independent PB MRD test exists.

AIM

To evaluate the analytical performance and clinical relevance of the **MiSelect R II System**[1,2] — a microfluidic rare-cell imaging platform for PB MRD detection in AML.

METHOD

MiSelect R II System Workflow



Leukemia-associated immunophenotypes (LAIPs) Strategy[3]

LAIP Class	Markers
Asynchronous antigen expression	CD15, CD38, HLA-DR
Cross-lineage expression	CD7, CD19, CD56
Antigen overexpression	NG2

MRD Detection Thresholds[3,4]:

MiSelect R (PB): ≥ 5×10^{-7}
MFC (BM): ≥ 0.01%
RT-qPCR (BM/PB):
NPM1, KMT2A-r: ≥ 1×10^{-5}
RUNX1::RUNX1T1, CBFB::MYH11: ≥ 1×10^{-4}
KMT2A-PTD: ≥ 1×10^{-3}

RESULTS

Figure 1. Study Design: Cross-platform MRD Comparison and Outcome Analysis

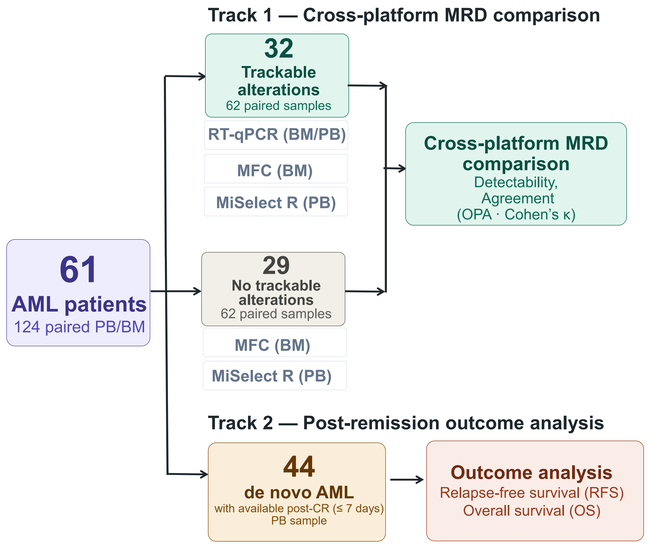


Table 1. Categorical Agreement between MRD Assays

Comparison	n	OPA (%; 95% CI)	PPA (%; 95% CI)	NPA (%; 95% CI)	Cohen's κ (95% CI)
RT-qPCR (PB) vs RT-qPCR (BM)	55	**89.1** (77.8–95.9)	86.1 (70.5–95.3)	94.7 (74.0–99.9)	**0.77** (0.60–0.94)
MiSelect R (PB) vs RT-qPCR (BM)	61	**73.8** (60.9–84.2)	79.5 (63.5–90.7)	63.6 (40.7–82.8)	**0.43** (0.19–0.67)
MiSelect R (PB) vs MFC (BM)	115	**55.7** (46.1–64.9)	91.2 (76.3–98.1)	40.7 (29.9–52.2)	**0.23** (0.07–0.39)

Cohen's κ interpretation: 0.61–0.80, substantial; 0.41–0.60, moderate; 0.21–0.40, fair.

Figure 2. MRD Detection Rate Across Platforms. (A) Samples with Genetic Alterations. (B) All Samples

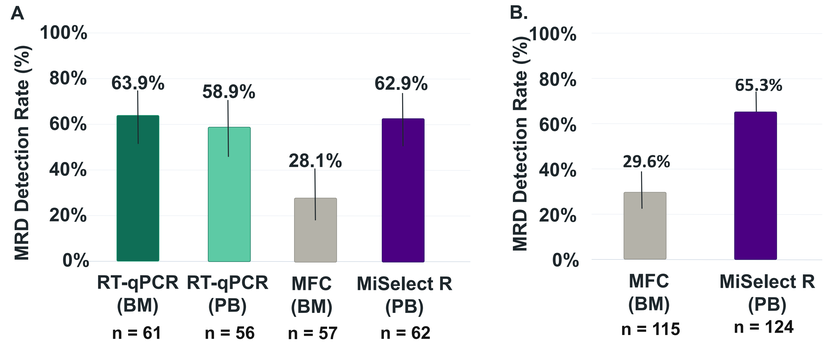
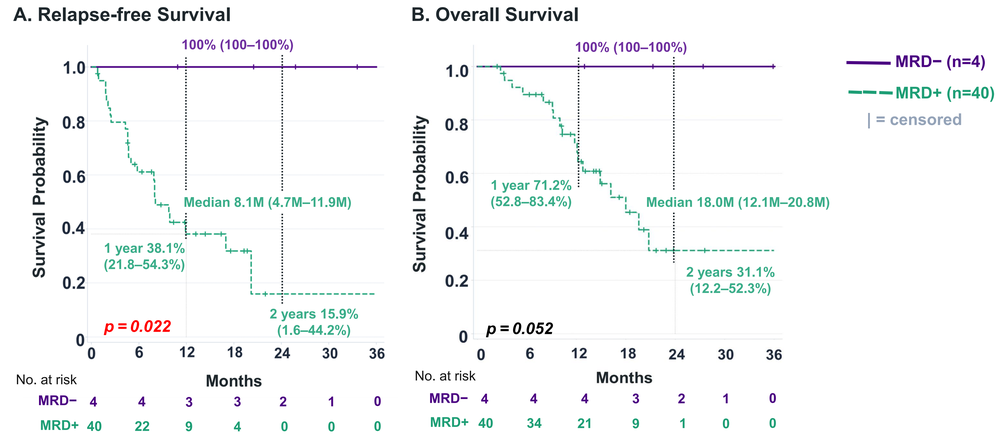


Figure 3. Outcomes according to MiSelect R (PB) MRD Status at End of Induction (post-CR ≤ 7 days)



CONCLUSIONS

- MiSelect R II enabled ultra-sensitive, genetic marker–independent MRD detection in peripheral blood, with detectability comparable to RT-qPCR and substantially higher than conventional BM-based MFC.
- MRD negativity assessed by MiSelect R (PB) was associated with superior RFS and OS, supporting its prognostic value in post-remission monitoring.
- As a non-invasive platform, MiSelect R II holds broad clinical applicability and supports the feasibility of PB MRD surveillance in AML.
- This preliminary result is limited by the small sample size; future clinical trials with larger patient populations will be needed to validate its clinical applicability.

REFERENCES

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