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RENI-1: A PROSPECTIVE, MULTICENTER REAL-WORLD STUDY OF NIRAPARIB AS FIRST-LINE MAINTENANCE THERAPY IN NEWLY DIAGNOSED ADVANCED OVARIAN CANCER

¹Jing Zuo*, ²Ke Wang, ³Zhumei Cui, ⁴Qingshui Li, ⁵Xiaodong Cheng, ⁶Zhong Zheng, ⁷Lixin Sun, ⁸Hui Zhang, ⁹Jun Zhang, ⁹Shuhe Wang, ¹⁰Dongyan Cao, ¹¹Lihong Chen, ¹²Hongqin Zhao, ¹³Wei Duan, ¹⁴Mia Zheng, ¹⁵Huafeng Shou, ⁶Jin Li, ¹⁶Yue Wang, ¹⁷Xiaoxiang Chen, ¹Lingying Wu. ¹National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; ²Tianjin Medical University Cancer Institute and Hospital, Tianjin, China; ³The Affiliated Hospital of Qingdao University, Qingdao, China; ⁴Shandong Cancer Hospital, Jinan, China; ⁵Women's Hospital, Zhejiang University School of Medicine, Hangzhou, China; ⁶Fudan University Shanghai Cancer Center, Shanghai, China; ⁷Shanxi Province Cancer Hospital/Shanxi Hospital Affiliated to Cancer Hospital, Chinese Academy of Medical Sciences/Cancer Hospital Affiliated to Shanxi Medical University, Taiyuan, China; ⁸The Fourth Hospital of Hebei Medical University, Shijiazhuang, China; ⁹The Seventh Medical Center, Chinese People's Liberation Army (PLA) General Hospital, Beijing, China; ¹⁰Peking Union Medical College Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; ¹¹Shaanxi Provincial People's Hospital, Shaanxi, China; ¹²The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, China; ¹³Beijing Obstetrics and Gynecology Hospital, Capital Medical University, Beijing, China; ¹⁴Sun Yat-sen University Cancer Center, Guangzhou, China; ¹⁵Zhejiang Provincial People's Hospital, Hangzhou, China; ¹⁶Henan Provincial People's Hospital, Zhengzhou, China; ¹⁷The Affiliated Cancer Hospital of Nanjing Medical University, Jiangsu Cancer Hospital, Jiangsu Institute of Cancer Research, Nanjing, China

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Introduction/Background Niraparib is the first PARP inhibitor to be approved for the first-line maintenance (1LM) treatment of all patients with newly diagnosed advanced ovarian cancer. The RENI-1 study (NCT04986371) was designed to evaluate the maintenance treatment patterns, efficacy and safety in ovarian cancer patients who received niraparib as 1LM therapy in the real world.

Methodology The study prospectively enrolled patients eligible for niraparib 1LM therapy. The primary endpoint was the maintenance treatment patterns, including initiation time of maintenance, starting dose of niraparib and maintenance regimens. Secondary endpoints included progression-free survival (PFS), chemotherapy-free interval, time to first subsequent treatment, overall survival, safety and quality of life.

Results From September 2021 to September 2022, 227 protocol patients were enrolled in 22 hospitals in China. Of the 227 patients, 210 (92.5%) had III-IV disease, 97 (42.7%) received neoadjuvant chemotherapy, 160 (70.5%) had a

complete response to platinum-based chemotherapy, 47 (20.7%) carried BRCA mutations (BRCAm), and 116 (51.1%) had homologous recombination deficiency (HRD). The median initiation time of maintenance was 7.6 weeks (range, 0.9–40 weeks), with 215 (94.7%) patients starting with 200 mg of niraparib and 218 (96.0%) patients receiving niraparib monotherapy. After a median follow-up of 16.8 months, median PFS (mPFS) was 24.2 months and 12-month PFS rate was 70.0% in the overall population. PFS benefit was observed regardless of BRCAm status and HRD status (table 1). Adverse events (AEs) of any grade were reported in 67.4% of patients, including 13.7% grade 3 or higher. AEs led to treatment interruption, dose reduction and discontinuation were 24.2%, 20.3% and 4.0%, respectively.

Conclusion Treatment patterns of niraparib 1LM are diverse in the real world, with BRCAm and HRD patients benefiting the most. The results of this prospective real-world study provide reassuring evidence of the activity and tolerability of niraparib maintenance therapy in newly diagnosed advanced ovarian cancer.

Disclosures All authors have declared no conflicts of interest.

329 THE SIGNIFICANCE OF DETECTING HYPERMETHYLATION LEVELS OF CD01 AND HOXA9 IN SERUM FOR EARLY DIAGNOSIS OF OVARIAN CANCER

¹Lei Li*, ¹Xiaopei Chao, ¹Linghua Kong, ²Lin Han, ²Suiqiong Lin, ²Hsianguy Chuang, ²Xiangyu Zhuang, ²Pei Liu. ¹Department of Obstetrics and Gynecology, National Clinical Research Center for Obstetric and Gynecologic Diseases, Peking Union Medical College Hospital, Beijing, China; ²Beijing Origin Poly Bio-Tec Co., Ltd, Beijing, China

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Introduction/Background Efforts to enhance the non-invasive detection of ovarian cancer (OC) are imperative, given the substantial improvement in survival rates associated with early diagnosis and treatment. This study aims to explore the clinical value of detecting hypermethylation levels of CD01 and HOXA9 in serum for the early diagnosis of OC.

Methodology A prospective study involving 141 patients undergoing surgery at Peking Union Medical College Hospital from May 2020 to April 2022 was conducted. Blood samples were collected preoperatively for CA125 level evaluation and DNA methylation testing. Simultaneously, comprehensive

Abstract 328 Table 1 Summary of median PFS, PFS6 and PFS12 by biomarker subgroup

Population	BRCAm status			HRD status		
	BRCAm (n=47)	BRCAwt (n=163)	BRCA unknown (n=17)	HRD (n=116)	HRP (n=67)	HRD unknown (n=44)
Median PFS, months (95% CI)	NR (NE-NE)	18.4 (15.2-21.7)	12.9 (10.2-15.7)	NR (NE-NE)	18.0 (13.6-22.4)	16.4 (11.6-21.2)
PFS6, months	95.7%	82.9%	81.3%	89.6%	81.0%	80.6%
PFS12, months	88.8%	66.0%	53.5%	77.0%	63.2%	60.5%

Abbreviations: PFS, progression-free survival; PFS6, 6-month PFS rate; PFS12, 12-month PFS rate; CI, confidence interval; BRCAm, BRCA mutations; BRCAwt, BRCA wild-type; NR, not reached; NE, not evaluable; HRD, homologous recombination deficiency; HRP, homologous recombination proficiency.

clinical information, biomarkers and transvaginal ultrasound (TVS) data were recorded. The clinical efficacy of DNA methylation detection for OC was assessed using the CISOVA methylation (CDO1 and HOXA9) real-time system (Beijing OriginPoly Bio-Tec Co., China) as a representative model.

Results Analysis of 90 ovarian cancers and 51 benign-masses confirmed by pathology revealed that age, menopausal status, CA125 levels and hypermethylation levels of CDO1 and HOXA9, either singly or in combination, were significantly higher in OC patients compared to the benign group ($P < 0.05$). Notably, among these detection protocols, the CISOVA (CDO1 and HOXA9) dual gene methylation exhibited a sensitivity of 87.8% and a specificity of 90.2%. The positive detection rate for early OC (FOGO stage I-II) using CISOVA was 80.0% higher than that of CA125 testing.

Conclusion Blood cell-free DNA methylation detection emerges as a promising and non-invasive method with highly sensitivity and specificity for OC diagnosis, outperforming current testing modalities for high-risk individuals. This approach holds the potential to significantly reduce invasive procedures, alleviate psychological burdens and surgical risks for patients, and improves compliance throughout the detection process.

Disclosures Conflict of Interest Disclosure Statement

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NAME: Lei Li

AFFILIATION: Department of Obstetrics and Gynecology, National Clinical Research Center for Obstetric & Gynecologic Diseases, State Key Laboratory for Complex, Severe and Rare Diseases, Peking Union Medical College Hospital

I have no potential conflict of interest to report

Signature: Lei Li Date: November 13th

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MEDX HRDETECTCDx PREDICTS THE RESPONSE OF NEWLY DIAGNOSED ADVANCED OVARIAN CANCER PATIENTS IN CHINA TO FIRST-LINE MAINTENANCE TREATMENT WITH NIRAPARIB

¹Jing Zuo*, ²Ke Wang, ³Zhumei Cui, ⁴Hui Zhang, ⁵Qingshui Li, ⁶Shuhe Wang, ⁷Lixin Sun, ⁴Jun Zhang, ⁸Min Zheng, ⁹Hongqin Zhao, ¹⁰Xiaoxiang Chen, ¹¹Xiaodong Cheng, ¹²Li Hong, ¹³Yang Gao, ¹³Wenhui Song, ¹³Yu Wang, ¹³Jiaxing Zhao, ¹³Zeyu Jiang, ¹³Yafei Zhang, ¹Lingyng Wu. ¹National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; ²Tianjin Medical University Cancer Institute and Hospital, Tianjin, China; ³The Affiliated Hospital of Qingdao University, Qingdao, China; ⁴The Fourth Hospital of Hebei Medical University, Shijiazhuang, China; ⁵Shandong Cancer Hospital, Jinan, China; ⁶The Seventh Medical Center, Chinese People's Liberation Army (PLA) General Hospital, Beijing, China; ⁷Shanxi Province Cancer Hospital/Shanxi Hospital Affiliated to Cancer Hospital, Chinese Academy of Medical Sciences/Cancer Hospital Affiliated to Shanxi Medical University, Taiyuan, China; ⁸Sun Yat-sen University Cancer Center, Guangzhou, China; ⁹The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, China; ¹⁰The Affiliated Cancer Hospital of Nanjing Medical University, Jiangsu Cancer Hospital, Jiangsu Institute of Cancer Research, Nanjing, China; ¹¹Women's Hospital, Zhejiang University School of Medicine, Hangzhou, China; ¹²Renmin Hospital of Wuhan University, Wuhan, China; ¹³MEDx (Suzhou) Translational Medicine Co., Ltd., Suzhou, China

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Introduction/Background The predictive value of HRD test for the efficacy of first-line (1L) maintenance therapy with PARPi in newly diagnosed advanced ovarian cancer (OC) patients has been confirmed by randomized controlled trials. However, research on the predictive value of HRD in real-world has been limited. We have developed MEDx HRDetectCDx test and validated its predictive value in a prospective, multicenter real-world study in China (NCT04986371).

Methodology The MEDx HRDetectCDx test was performed by capture-based targeted sequencing of ~42,000 genome-wide single nucleotide polymorphisms specific to Chinese population at $\pm 200x$ coverage and coding exons of 85 genes at $\pm 400x$ coverage. The HRD score was calculated by analyzing LOH, TAI and LST. A score ≥ 43 (cut-off) is considered positive. The analytical performance of the HRDetectCDx was evaluated by comparing to the Myriad myChoice (Myriad test). The predictive impact of the HRD score on niraparib efficacy was evaluated in the prospective RENI-1 study, which enrolled OC patients from 22 centers in China who received niraparib as 1L maintenance therapy between 2021 and 2022. The date of PFS data cut-off was 18 October 2023.

Results The positive percentage agreement between the HRDetectCDx panel and the Myriad test is 89.5%, the negative percentage agreement is 93.3% and the overall percent agreement is 91.2%. 227 eligible patients were enrolled and 122 patients underwent HRDetectCDx test with 92 evaluable for HRD status. 20 (16.4%) had BRCAm and 53 (43.4%) had HRD. Median PFS was not reached (NR) and 14.4 months in the HRD and HRp groups (HR 0.51; 95% CI 0.27–0.97), respectively. In the HRD group, median PFS was NR for BRCAm and 18.1months for BRCAwt/HRD (HR 0.46; 95% CI 0.15–1.39).

Conclusion The MEDx HRDetectCDx demonstrated high consistency with Myriad test and was prospectively validated for predictive value in 1L maintenance therapy with niraparib in the real-world setting.

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UNVEILING THE PROGNOSTIC SIGNIFICANCE OF PROTEIN EXPRESSION IN ADVANCED HGSO: A COMPARATIVE STUDY BETWEEN LONG-TERM SURVIVORS AND EARLY-RECURRENT/MORTAL PATIENTS

¹Ji-Won Ryu*, ²Jangkyum Kim, ³Jue Young Kim, ³Ha-Yoen Shin, ³Jae-Hoon Kim. ¹Graduate School of Medicine, Yonsei University, Seoul, South Korea; ²Department of Data Science, Sejong University, Seoul, South Korea; ³Department of Obstetrics and Gynecology, Gangnam Severance Hospital, Yonsei University College of Medicine, Seoul, South Korea

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Introduction/Background High-grade serous ovarian cancer, despite its high lethality, lacks reliable biomarkers for predicting poor prognosis, and Limited progression has been made in personalized treatment. Genomic profile-based targeted therapy has not met expectations, as genomic alterations alone do not exclusively determine cancer cell phenotypes. Protein expression critically influences cellular processes. Recognizing proteomic alterations is even more crucial. This study proposes a novel technique, utilizing statistical deviation and unsupervised learning to select protein factors determining ovarian cancer prognosis.

Methodology The good prognosis group comprised 24 cases, characterized by no relapse for 5 years after the initial treatment or relapse with no further progression for the