Abstract 2022-RA-618-ESGO Table 1 Demographic and clinical characteristic of the primary and stratified cohorts

<table>
<thead>
<tr>
<th>Primary study cohort</th>
<th>Niraparib pre-1LM approval cohort (index dates before 23April2020)</th>
<th>Niraparib post-1LM approval cohort (index dates on or after 23April2020)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age at index (Q1, Q3), years</td>
<td>65.0 (62.0, 75.0)</td>
<td>67.5 (62.0, 75.0)</td>
</tr>
<tr>
<td>Primary tumor type, %</td>
<td>60 (16.0%)</td>
<td>17 (18.9%)</td>
</tr>
<tr>
<td>Stage at initial EOC diagnosis, %</td>
<td>81 (20.5%)</td>
<td>25 (8.4%)</td>
</tr>
<tr>
<td>i.i.d.</td>
<td>20 (5.3%)</td>
<td>55 (6.9%)</td>
</tr>
<tr>
<td>II</td>
<td>188 (50.3%)</td>
<td>155 (18.4%)</td>
</tr>
<tr>
<td>III</td>
<td>130 (44.9%)</td>
<td>86 (30.3%)</td>
</tr>
<tr>
<td>Unknow/no documented</td>
<td>36 (9.5%)</td>
<td>28 (9.9%)</td>
</tr>
<tr>
<td>PECRC mutation status, %</td>
<td>10 (2.6%)</td>
<td>10 (2.6%)</td>
</tr>
<tr>
<td>Residual disease status following initial surgery for EOC, %</td>
<td>59 (15.8%)</td>
<td>51 (18.0%)</td>
</tr>
<tr>
<td>No disease residual</td>
<td>59 (15.8%)</td>
<td>51 (18.0%)</td>
</tr>
<tr>
<td>No visible disease</td>
<td>62 (16.9%)</td>
<td>24 (26.7%)</td>
</tr>
<tr>
<td>Visible disease</td>
<td>148 (43.9%)</td>
<td>36 (36.7%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>23 (6.2%)</td>
<td>15 (5.2%)</td>
</tr>
<tr>
<td>HRD status, %</td>
<td>9 (2.3%)</td>
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</tr>
<tr>
<td>HRD-positive</td>
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<td>3 (1.2%)</td>
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Demographic characteristics

Patients with records in academic and community practices are counted in both categories; therefore, percentages may sum to more than 100.

Results with counts less than 5 are masked by combining categories.

Data do not differentiate between somatic and germline mutations.


Introduction/Background

Ovarian cancer is a common procedure in ovarian cancer cytoreductive surgeries. The decision-making process greatly varies between surgical teams and largely depend not only on training but also traditional aspects and beliefs, surgeons’ preferences, medicolegal aspects and local governance protocols. The objective of the present study was to define and validate an anastomotic leak prognostic score based on previously described and reported anastomotic leak risk factors (https://n9.cl/ova-leakscore).

Methodology

This is a prospective, multicentre cohort study that included patients who underwent cytoreductive surgery for primary advanced or relapsed ovarian cancer with colorectal resection and anastomosis between January 2011 and June 2021. Data from patients already included in the previous predictive model were not considered in the present analysis.

Results

848 out of 1159 recruited patients were finally included in the multivariable logistic regression model validation. The AUC of the new cohort was 0.63. Considering a cut-off point of 22.1% to be ‘positive’ (to get a leak) this would provide a sensitivity of 0.45, specificity of 0.80, predictive positive value of 0.09 and predictive negative value of 0.97 for anastomatic leak. If we consider this cut-off point to select patients for bowel diversion, up to 22.5% of the sampled patients would undergo a diverting ileostomy and 47% (18/40) of the anastomatic leaks would be ‘protected’ with the stoma. Nevertheless, if we consider only the ‘clinical criteria’ for performing or not a diverting ileostomy, only 12.5% (5/40) of the leaks would be ‘protected’ with a stoma, with a rate of diverting ileostomy of up to 24.3%.

Conclusion

Compared with subjective clinical criteria, the use of a predictive model for anastomotic leak improves the selection of patients who would benefit from a diverting ileostomy without increasing the rate of stoma use.

Table 1. Demographic and clinical characteristic of the primary and stratified cohorts

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Introduction

Overexpression of PDE1A is a predictive biomarker for platinum resistance and poor prognosis in epithelial ovarian cancer by regulating cell cycle


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Introduction/Background

Phosphodiesterase 1A (PDE1A) belongs to a class of phosphohydrolatic enzymes that modulate the intensity of intracellular second messenger signaling and result in the integration of Ca2+ and cyclic nucleotide mediated in various disease such as cancers in expression and clinicopathological features, while its role in epithelial ovarian cancer (EOC) has not been clarified yet. Therefore, in this study we aim to evaluate the function, molecular mechanism and clinicopathological significance of PDE1A in EOC.

Methodology

The qPCR, western blotting and public data sets were used to evaluate the expression level of PDE1A. Also, expression levels of PDE1A and clinicopathological characteristics were evaluated by immunohistochemistry staining of EOC, borderline, benign and normal epithelial tissues. Its functional role and association with cell cycle were evaluated in EOC cell lines.
Results High mRNA and protein levels of PDE1A were observed in EOCs compared to borderline, benign and normal nonadjacent ovarian epithelial tissues ($p < 0.001$). Also, high expression of PDE1A was significantly associated with serous ($p = 0.023$), high grade ($p = 0.012$), advanced stage FIGO stage ($p < 0.001$), and resistance to platinum based chemotherapy ($p < 0.001$) EOCs. Importantly, high expression level of PDE1A was indicated as a prognosis predictive biomarker by Cox multivariate analysis. Specifically, we observed that PDE1Apromoted G2/M transition by regulating cyclin B1 transcription.

Conclusion Taken together, our findings suggested that PDE1A is a promising biomarker for prediction of prognosis and resistance to platinum based chemotherapy in EOC patients.

Introduction/Background PARP inhibitors resistance is a problematic step in epithelial ovarian cancer (EOC) management and sequencing strategies should be carried out to overcome it. In this context, to lack of data, our study evaluated the role of a non-platinum doublet pegylated liposomal doxorubicin(PLD)/trabectedin in ovarian cancer platinum-sensitive patients who experienced disease progression under PARP inhibitors maintenance.

Methodology This is a case-control study including patients with recurrent EOC treated between 2016-2021 who progressed under PARP inhibitors maintenance. Data of patients, treated with PLD/trabectedin were matched 1:1 with a series of patients who received platinum-based treatment. The study outcomes were: overall clinical benefit (including complete, partial and stable response), progression-free survival(PFS) and overall survival(OS). The safety of both treatments was also evaluated.

Results 26 patients in both groups were analyzed. Clinical benefit was achieved in 15 (57%) patients in study group and 17 (65%) in control one ($p = 0.38$). Patients receiving PLD/trabectedin had 5 months of PFS, compared with 5 months of patients treated with platinum-based treatment ($p = 0.62$). OS of the entire population was 84 months (95% CI = 68–99), with no significant difference between the experimental and control group (75 vs. 87 months, $p = 0.30$). No clinically relevant differences were found in terms of safety.

Conclusion PLD/trabectedin might be as effective as a platinum-based treatment in patients experiencing disease progression while on PARP inhibitors maintenance, with acceptable toxicity profile. Therefore, it could be a good therapeutic option in this setting, sparing platinum compounds for subsequent relapse.

Introduction/Background The vagal nerve may have protective roles cancer. Its activity is indexed by heart-rate variability (HRV). This study aimed to examine the prognostic role of HRV in women with ovarian cancer.

Methodology This was a retrospective comparative cross-sectional study. Information obtained from medical records of patients with histologically confirmed ovarian cancer treated at a single institute, between the years 2014–2021. Background variables that were obtained included age, stage, white blood cells count (WBC) date of death or date of last contact, which ever came first. HRV, the index of vagal nerve activity, was derived from patients’ 10 sec ECG near diagnosis.

Results 104 women were included in our final cohort. Mean age was 64.7, 11.4%, 4.9%, 54.5%, 29.3% of the women were stage I,II, III and IV respectively. After controlling for known prognostic factors log-HRV tended to significantly predict a lower risk of death (R.R = 0.20, 95% CI: 0.04 – 1.06) as well as the ratio of HRV/WBC.