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VALIDATION STUDY OF THE 'NOGGO-GIS ASSAY' BASED ON OVARIAN CANCER SAMPLES FROM THE FIRST-LINE PAOLA-1/ENGOT-OV25 PHASE-III TRIAL

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Introduction/Background Several clinical trials have demonstrated that the maintenance with a PARP inhibitor with or without bevacizumab following platinum-based therapy improved PFS in advanced ovarian cancer patients. The benefit was significant greater in homologous recombination deficient (HRD) patients according to Myriad myChoice test. The PAOLA-1 olaparib+bevacizumab maintenance regimen was approved in USA/Europe/Japan for HRD and BRCA positive patients. Using sample from the PAOLA-1/ENGOT-ov25 we evaluated the novel 'NOGGO-GIS ASSAY' as part of the ENGOT HRD-European-Initiative.

Methodology A hybrid capture NGS assay based on the Agilent XTH2 chemistry and SNP backbone, was developed for the detection of somatic driver mutations in key cancer genes, BRCA1/2 mutations, HRR gene mutations and HRD in combination with a bioinformatic analysis pipeline based on publicly available tools. The assay was clinically validated using 468 ovarian cancer samples from the PAOLA-1/ENGOT-ov25 trial.

Results Here we report the first results of the 'NOGGO-GIS ASSAY' validation compared to the Myriad myChoice clinical trial. The assay is based on widely available hybrid capture chemistry, to cover 57 genes and approx. 20.000 SNP loci, automated for parallel processing of 48 samples per run and requires 50 ng of genomic DNA extracted from tissue section with at least 30% of tumor content with a low failure rate of around 5%. The performance characteristics of the NOGGO GIS Assay are comparable to the PAOLA-1/ENGOT-ov25 clinical trial assay. The NOGGO GIS Assay showed a similar impact of olaparib +bevacizumab on PFS with a comparable Hazard Ratio for HRD positive patients.

Conclusion The 'NOGGO-GIS ASSAY' based on widely available components was validated on clinical trial samples showing performance characteristics similar to the clinical trial

assay. The low failure rate, low input material required, HRD and BRCA1/2 and mutation status in 57 clinically relevant genes makes this a highly attractive option for analysis of FFPE samples.

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EXPRESSION OF P16 AND KI67 IN CERVICAL HIGH GRADE SQUAMOUS INTRAEPITHELIAL LESION IN WOMEN UP TO 30 YEARS OLD

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Introduction/Background Immunohistochemistry is a technique that evaluates the association of biomarkers with morphological changes, offering a higher level of reproducibility, sensitivity, and specificity in the diagnosis of many neoplasms, with p16 associated with high-risk HPV and ki-67 with cell multiplication. The aim is to determine the expression of p16 and Ki67 in high-grade intraepithelial lesions in patients aged 30 years or younger and correlate clinical outcome.

Methodology Retrospective cross-sectional study, that analyzes women diagnosed with HSIL treated at the gynecology outpatient clinic of the University Hospital. Demographic and clinical data and follow-up were collected from the hospital records. Descriptive analyses were expressed by measures of central tendency and dispersion. To identify possible associations between qualitative variables, the chi-square test was used. Spearman correlation were conducted between the variables of interest.

Results The average age of the participants was 27 years, and the majority were healthy 49 (72.1%) and non-smokers 47 (69.1%). Only 21 (30.9%) of them had completed high school and 5 (7.4%) had higher education. Considering the anatomopathological characteristics, most participants had cervical intraepithelial neoplasia (CIN) III (77.9%) and, to a lesser extent, cervical intraepithelial neoplasia (CIN) II (22.1%). Practically all were positive for P16INK4a and Ki67 (97.1% and 98.5%, respectively), and 65 (95.6%) were discharged from the outpatient clinic, with only 1 (1.5%) relapsed during follow-up. The analyzes did not show correlations between any of the variables of interest (e. g. age, age less than or equal to 30 years, parity, smoking and immunosuppression), with the outcomes studied (positive P16INK4a and Ki67) (Spearman correlations, $p > 0.05$ for all the analyses). Furthermore, P16INK4a and Ki67 were positively related (Spearman, $\rho = 0.702$, $p \leq 0.001$).

Conclusion It was not possible to prove that the use of biomarkers helps in the diagnosis and prognosis of precursor lesions in women aged up to 30 years.

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PAGET'S DISEASE OF THE NIPPLE

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