2022-RA-873-ESGO VALIDATION STUDY OF THE 'NOGGO-GIS ASSAY' BASED ON OVARIAN CANCER SAMPLES FROM THE FIRST-LINE PAOLA-1/ ENGOT-OV25 PHASE-III TRIAL

[1]Eva-Maria Willing, [2,3]Claudia Vollbrecht, [1]Christine Voessing, [1]Peggy Weist, [2]Simon Schallenberg, [1]Balazs Jori, [1]Markus Tiemann, [4]Guillaume Bataillon, [5]Philipp Harter, [6]Sandro Pignata, [7,8]Antonio Gonzales Martin, [9]Ignace Vergote, [10]Nicoletta Colombo, [11]Christian Marth, [1]Tobias Berg, [1]Bettina Kah, [1]Johanna Herbst, [12]Trine Jakobi Noettrup, [1]Markus Falk, [1]Kathrin Arndt, [13,14]Isabelle Ray-Coquard, [15]Andreas Polten, [1]Robert Bernstein, [1]Franziska Selzam, [1]Judith Pirngruber, [1]Stefanie Schmidt, [2,3]Michael Hummel, [16,3]Jalid Sehouli, [2]David Horst, [16,3,14]Elena Ioana Braicu, [14]Eric Pujade Lauraine, [1,3]Katharina Tiemann, [1,3]Lukas C Heukamp. *[1]Institut für Hämatopathologie, Hamburg, Germany; [2]Institute of Pathology, Charité-Universitätsmedizin Berlin, Corporate Member of Freie Universität Berlin, Humboldt-Universität Zu Berlin and Berlin Institute of Health, Berlin, Germany; [3]Nord-Ostdeutsche Gesellschaft für Gynäkologische Onkologie NOGGO e. V., Berlin, Germany; [4]Laboratoire de pathologie de l'oncopole-IUCT, Touluose, France; [5]Kliniken Essen Mitte, Essen, Germany; [6]Department of Urology and Gynecology, Istituto Nazionale Tumori IRCCS Fondazione G. Pascale, and Multicenter Italian Trials in Ovarian Cancer and Gynecologic Malignancies (MITO), Naples, Italy; [7]Medical Oncology Departament, Clinica Universidad de Navarra, Madrid, Spain; [8]GEICO, Madrid, Spain; [9]Leuven Cancer Institute, University Hospital Leuven, Leuven, Belgium; [10]European Institute of Oncology, Milan, Italy; [11]Department of Obstetrics and Gynecology, Medical University Innsbruck, Innsbruck, Austria; [12]Copenhagen University Hospital, Copenhagen, Denmark; [13]Centre Léon BERARD, and University Claude Bernard Lyon I, Lyon, France; [14]ARCAGY-GINECO, Paris, France; [15]Agilent Technologies Sales and Services GmbH und Co.KG, Waldbronn, Germany; [16]Charité-Universitätsmedizin Berlin, Corporate Member of Freie Universität Berlin, Humboldt-Universität Zu Berlin and Berlin Institute of Health, Berlin, Germany*

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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.

2022-RA-1023-ESGO EXPRESSION OF P16 AND KI67 IN CERVICAL HIGH GRADE SQUAMOUS INTRAEPITHELIAL LESION IN WOMEN UP TO 30 YEARS OLD

[1]Giovana Fontes Rosin, [2]Valentino Antonio Magno, [3]Suzana Arenhart Pessini. *[1]Gynecology and Obstetrics Postgraduate Programme. Universidade Federal do Rio Grande do Sul., Porto Alegre, Brazil; [2]Gynecology, Universidade Federal do Rio Grande do Sul. Hospital de Clinicas de Porto Alegre, Porto Alegre, Brazil; [3]Gynecology, Universidade Federal do Rio Grande do Sul. Hospital de Clinicas de Porto Alegre. Gynecology and Obstetrics Postgraduate Programme, PORTO ALEGRE, Brazil*

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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, $\rho=0.702$, $p\leq0.001$).

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.

2022-RA-1061-ESGO PAGET'S DISEASE OF THE NIPPLE

[1]Mohammed Karam Saoud, [2]Hanae Taghzouti. *[1]CHU hassan II fes, CHU hassan II, Morocco; [2]CHU hassan II fes, fes, Morocco*

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