#119 PREDICTION OF GERMLINE BRCA 1/2 GENES PATHOGENETIC VARIANTS FROM HEALTHY OVARIES ULTRASOUND IMAGES: RADIOGENOMICS AS AN INNOVATIVE TOOL TO PREVENT BRCA-RELATED CANCERS

Camilla Nero*, Francesca Ciccarone, Luca Boldrini, Jacopo Lenkowicz, Huong Elena Tran, Maria Teresa Giudice, Francesca Sillano, Gloria Anderson, Floriana Camarda, Ida Paris, Angelo Minucci, Maria De Bonis, Martina Rinelli, Giulia Zinicola, Iolanda Mozzetta, Tina Pasciuto, Diana Giannarelli, Vincenzo Valentini, Antonia Testa, Giovanni Scambia. *Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy*

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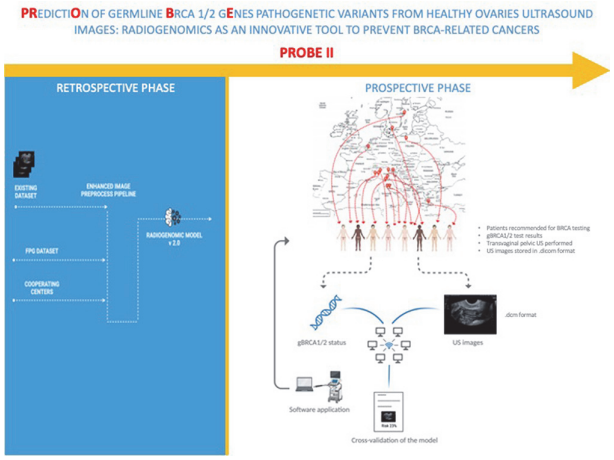
Introduction/Background Current indications for BRCA 1/2 testing based on a priori BRCA probability thresholds are ineffective as most of the carriers remain undiagnosed. Data regarding the cost-effectiveness of a population-based BRCA mutation screening are still controversial. Radiomics is an emerging tool for large scale quantitative analysis of features from standard diagnostic imaging and has been applied also to identify gene mutational status.

Our group already showed the feasibility of performing a radiomic analysis of US images of normal ovaries to predict germline BRCA 1/2 genes status. Models performances on the testing set were reasonably encouraging.

Moreover, we performed a cost-effective analysis showing that combining clinical criteria with the radiogenomic model would have a massive effect after only one generation in detecting carriers in the general population with only a small cost increment. The present study aims at improving the preprocessing pipeline on a larger internal dataset and at cross-validating the predictive model on US images acquired prospectively in an observational multicenter study (NCT05769517).



Abstract #119 Figure 1 PROBE II

Methodology We will conduct a multicenter observational study involving 14 international centers. The study is composed of:

- A retrospective phase aimed at defining and implementing a proper and fine-tuned image preprocessing pipeline on the existing dataset and enlarging dataset size (at least 300 patients) with new real images and apply data augmentation techniques, deep neural network models combined with the aforementioned handcrafted imaging features from radiomics analysis.

- A prospective phase aimed at further cross-validating the predictive model on US images acquired prospectively in an observational multicenter study. 1.000 patients are expected to be enrolled.

Results Results are expected by the end of 2026.

Conclusion If validated as a reliable model, the integration of this radiogenomic model with current clinical/familiar criteria could represent an innovative, cost-effective approach towards ovarian cancer prevention across generations.

Disclosures The authors declare no disclosures.

#124 A PHASE II, MULTICENTRE, OPEN-LABEL STUDY OF ABEMACICLIB AND LETROZOLE IN PATIENTS WITH ESTROGEN RECEPTOR-POSITIVE RARE OVARIAN CANCER

Tine Ottenbourgs*, Els Van Nieuwenhuysen. *UZ Leuven, Leuven, Belgium*

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Introduction/Background Low-grade serous ovarian cancer (LGSOC) and adult-type granulosa cell tumor (aGCT) are rare ovarian malignancies, accounting for about 8% and 5% of all ovarian cancers, respectively. These subtypes of ovarian cancer will often be treated with conventional chemotherapy, although response rates are disappointing. Due to these low response rates, the search for alternative treatment strategies is crucial. The cyclin-dependent kinase 4/6 (CDK4/6) inhibitor abemaciclib in combination with an aromatase inhibitor (e.g. letrozole) has remarkably improved the outcome of patients with estrogen receptor-positive (ER+) breast cancer. ER+ ovarian cancer shows variable responses to aromatase inhibitors, which hopefully can be improved by the same drug combination.

Methodology The study is a phase 2, multicentre, open-label, single-arm clinical trial of abemaciclib (150 mg BD) and letrozole (2.5 mg OD) in patients with advanced, recurrent and/or metastatic ER+ ovarian cancer who failed one line of platinum-based chemotherapy for advanced or recurrent disease. One cohort will include LGSOC patients and another cohort aGCT patients. Up to 50 patients with ER+ tumors will be included per cohort. Enrolment will take place at 3 Belgian, 5 French, 5 Spanish and 3 Dutch sites. The primary objective of this study is to determine overall response rate to abemaciclib and letrozole, according to RECIST v1.1. Secondary objectives include DOR, CBR, PFS, OS and adverse events. Additionally, patient-reported quality of life will be assessed by applying EQ-5D-5L and EORTC QLQ-C30 questionnaires. Exploratory aims include assessing blood and tissue biomarkers (such as ER, PR, ctDNA, mutation burden, methylation signatures etc.) for association with clinical benefit and response rate. An interim analysis will be performed at week 24 to assess efficacy after 15 patients per cohort become evaluable. Thirty additional patients per cohort will be included when the response rate is more than 1 in 15 evaluable patients.

Results /

Conclusion /

Disclosures This trial is supported by Eli Lilly and Company which supplies the study drug abemaciclib and Kom Op Tegen Kanker (Stand Up Against Cancer) which provides a grant.

#140 SURVEILLANCE OF CERVICAL INTRAEPITHELIAL NEOPLASIA GRADE 2 WITH DUAL P16/KI-67 IMMUNOCYTOCHEMISTRY STAINING. TRIAL PROTOCOL AND PRELIMINARY REPORT

Kimon Chatzistamatiou*, Vasilios Theodoulidis, Dimitrios Zouzoulas, Panagiotis Tzitzis, Anastasia Sarieva, Iliana Sofianou, Eleni Mpili, Themistoklis Mikos, Grigorios Grimbizis, Dimitrios Tsolakidis. *Aristotle University of Thessaloniki, Thessaloniki, Greece*

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Introduction/Background Cervical intraepithelial neoplasia (CIN) grade 2 is considered a high-grade squamous intraepithelial lesion requiring surgical treatment. Excisional cervical procedures, though, have been linked to an increased risk of preterm birth in subsequent pregnancies. Therefore, and given the fact that the vast majority of CIN2 cases will regress, there is a tendency to avoid surgical treatment for women who wish fertility preservation. The aim of the CIN2DIN study is to determine the diagnostic accuracy of P16/Ki-67 immunocytochemistry (ICC) for the timely detection of CIN3 +, among women with untreated CIN2, compared to cytology.

Methodology According to the study design, women with biopsy confirmed CIN2, after written informed consent, will be subjected to cervicovaginal sampling for p16/Ki-67 ICC (CINtec PLUS, Roche laboratories AG, Mannheim, Germany), cytology and high-risk Human Papillomavirus (hrHPV) testing (cobas® HPV Test, Roche Molecular Systems, Pleasanton, CA, USA) (t=0). After six months (t=1), participants will be subjected to colposcopy, and, cervicovaginal sampling for cytology and p16/Ki-67 ICC. After 12 months (t=2) participants will be subjected to colposcopy, and, to cervicovaginal sampling for hrHPV testing, cytology and p16/Ki-67 ICC. Participants will be also examined after 18 and 24 months (t=3, t=4, respectively). Examinations at t=3 and t=4 will be similar to t=1, and t=2 respectively. All women after visit t=4 exit the study and are referred to treatment according to the local guidelines.

Results To date 5 women with biopsy proven CIN2 have been recruited. Those women have been subjected to pap test, hrHPV testing, and p16/Ki-67 ICC.

Conclusion The CIN2DIN study is original and innovative. So far, no studies have been conducted on the value of P16/Ki-67 ICC for CIN2 surveillance. If the study identifies high correlation of P16/Ki-67 ICC to colposcopy, larger studies could be designed to investigate longer-term reassurance for the surveillance of women with untreated CIN2 without colposcopy.

Disclosures The authors have nothing to disclose

#145 INTERNATIONAL VARIATIONS IN POST-OPERATIVE MORBIDITY AND MORTALITY FOLLOWING GYNAECOLOGICAL ONCOLOGY SURGERY (GO SOAR1)

[1,2]Faiza Gaba*, [3]Karen Ash, [4]Oleg Blyuss, [5]Nicolò Bizzarri, [6]Paul Kamfwa, [7]Allison Saiz, [2]Shantini Paranjothy, [8]David Cibula. *[1]The Royal London Hospital, London, UK; [2]University of Aberdeen, Aberdeen, UK; [3]Aberdeen Royal Infirmary, Aberdeen, UK; [4]Queen Mary University Of London, London, UK; [5]Fondazione Policlinico Universitario A. Gemelli, IRCCS, UOC Ginecologia Oncologica, Dipartimento per la salute della Donna e del Bambino e della Salute Pubblica, Rome, Italy; [6]Cancer Diseases Hospital, Lusaka, Zambia; [7]Northwestern University, Chicago, USA; [8]Charles University and General University Hospital, Prague, Czech Republic*

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Introduction/Background Gynaecological malignancies affect women in low and middle income countries (LMICs) at disproportionately higher rates compared with high income countries (HICs), but little is known about global variations in access, quality and outcomes in gynaecological cancer care. The aim if our study was to evaluate international variation in post-operative morbidity and mortality following gynaecological oncology surgery between LMIC and HIC settings.

Methodology Multicentre, international prospective cohort-study of women undergoing surgery for primary ovary/uterus/cervix/vulva/vagina/gestational trophoblastic malignancies (NCT04579861). Multilevel logistic-regression determined relationships within three-level nested models of patients within hospitals/countries.

Results We enrolled 1820 patients from 73 hospitals in 27 countries (1078 (59.2%) high income countries, 453 (24.9%) upper middle income countries, 174 (9.6%) lower middle income countries, 115 (6.3%) low income countries). Mean follow-up was 58.7 and 55.7 days from date of surgery in LMICs/HICs respectively. Overall-morbidity (Clavien-Dindo I-IV) for all tumour-groups was 34.7% (233/672) and 33.5% (338/1009), whilst mortality 2.1% (14/672) versus 1% (10/1009) for LMICs/HICs respectively. Minor-morbidity (Clavien-Dindo I-II) for all tumour-groups was 26.5% (178/672) and 26.5% (267/1009), whilst major-morbidity (Clavien-Dindo III-V) 8.2% (55/672) and 7% (71/1009) for LMICs/HICs respectively. Higher minor-morbidity was associated with previous laparoscopic surgery (OR=1.435, 95%CI=1.046–1.966, p=0.025), COVID-19 positive status (OR=5.025, 95% CI=1.262–20.008, p=0.022), pre-operative mechanical bowel preparation (OR=1.474, 95%CI=1.054–2.061, p=0.023), longer surgeries (OR=1.253, 95%CI=1.066–1.472, p=0.006), greater blood loss (OR=1.274, 95%CI=1.081–1.502, p=0.004), and occurrence of intra-operative complication (OR=2.203, 95%CI=1.498–3.241, p<0.001). Minimal-access-surgery was protective against minor-morbidity (OR=0.522, 95%CI=0.371–0.735, p≤0.001). Higher major-morbidity was associated with longer surgeries (OR=1.37, 95%CI=1.128–1.664, p=0.002), greater blood loss (OR=1.398, 95% CI=1.175–1.664, p≤0.001), and seniority of lead-surgeon with junior surgeons three times more likely to have a major-