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 cervicavaginal 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, cervicavaginal sampling for cytology and p16/Ki-67 ICC. After 12 months \( t=2 \), participants will be subjected to colposcopy, and, to cervicavaginal sampling for hrHPV testing, cytology and p16/Ki-67 ICC. Participants will be also examined after 18 and 24 months \( t=3, t=4 \). Examinations at \( t=3 \) and \( t=4 \) will be similar to \( t=1, t=2 \) 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.

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

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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 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 (NCT04379861). 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 \( (OR=2.030, 95\% CI=1.498–3.241, p<0.001) \). 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-
Results As a result of this analysis, STREAM-II is planned as a consecutive prospective, single-arm, non-interventional, multicenter trial validating the predictive score established within the present study. Following confirmation, STREAM-III is planned to be a randomized, multicenter phase III trial evaluating CRS in EC. Conclusion STREAM-I represents the first step towards Level I evidence for CRS in EC by identifying patients who most likely benefit from a radical surgical approach. STREAM-I will provide information to develop consecutive trials prospectively evaluating the impact of CRS in EC (STREAM-II-III). 

Disclosures No direct conflict of interest for this surgical trial exists. Further relation to companies have been disclosed and uploaded.

Introduction/Background Endometrial cancer (EC) is the most common gynaecological cancer in Europe with approximately 20% of patients being diagnosed in advanced stage (FIGO III-IV). Until now, only few studies exist for cytoreductive surgery (CRS) in advanced stage reporting of complete cytoreduction in 18–75% cases. Evidence for EC from large multicenter analyses data is missing and the indication for CRS is widely based on individual and/or institutional decision algorithms. 

Methodology STREAM-I/AGO-OP

11ENGOT-en22 is a retrospective, non-interventional, multicenter study aiming to identify preoperative clinical and translational selection criteria for cytoreductive surgery in endometrial cancer – step 1 of the STREAM (surgical treatment in advanced and recurrent endometrial cancer management) initiative. 

Disclosures None.

#172 STREAM-I/AGO-OP.11/ENGOT-EN22: EVALUATION OF PREOPERATIVE CLINICAL AND TRANSLATIONAL SELECTION CRITERIA FOR CYTOREDUCTIVE SURGERY IN ENDOMETRIAL CANCER – STEP 1 OF THE STREAM (SURGICAL TREATMENT IN ADVANCED AND RECURRENT ENDOMETRIAL CANCER MANAGEMENT) INITIATIVE

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Introduction/Background Single agent chemotherapies are commonly used in platinum-resistant ovarian cancer, but outcomes are generally poor. Cortisol, which acts by binding to the glucocorticoid receptor (GR), can suppress apoptotic pathways used by cytotoxic agents. The GR is abundantly expressed in ovarian tumours and high GR expression is associated with poor outcomes. Data indicate that the selective GR modulator relacorilant can reverse cortisol’s anti-apoptotic effects, thereby enhancing chemotherapy efficacy. In a phase 2 study in patients with recurrent, platinum-refractory or platinum-resistant ovarian cancer, intermittently dosed relacorilant + nab-paclitaxel showed clinically meaningful improvement in progression-free survival (PFS), duration of response (DoR), and a trend toward improved overall survival (OS) without increased side effect burden compared to nab-paclitaxel monotherapy. This phase 3 study aims to confirm the findings of the phase 2 study in a larger patient population. 

Methodology ROSELLA (GOG-3073, ENGOT-OV72/MITO): A PHASE 3 STUDY OF RELACORILANT + NAB-PACLITAXEL VS. NAB-PACLITAXEL IN ADVANCED, PLATINUM-RESISTANT OVARIAN CANCER

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Abstracts