withdraw from the study. The primary endpoint is progression-free survival (PFS) as assessed by the investigator in the all-comers population and the dMMR population per RECIST version 1.1. Secondary efficacy endpoints are PFS assessed by blinded independent central review per RECIST version 1.1, overall survival, objective response rate, duration of response, disease control rate, safety and tolerability, and patient-reported outcomes.

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Encore statement: This data is presented on behalf of the original authors with their permission. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, May 29–31, 2020, Virtual.

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Drs. Hanker and Valabrega have nothing to disclose.

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403 PHASE 3 TRIAL OF TUMOR TREATING FIELDS CONCOMITANT WITH WEEKLY PACLITAXEL FOR PLATINUM-RESISTANT OVARIAN CANCER: ENGOT-OV50/GOG-329/INNOVATE-3

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Introduction/Background Tumor Treating Fields (TTFields) are a non-invasive, antimitotic cancer therapy. The Phase 2 INNOVATE study demonstrated safety of TTFields/weekly paclitaxel in 31 PROC (platinum-resistant ovarian cancer) patients (Vergote Gyn Onc 2018); efficacy: median PFS 8.9 months, 25% partial response,71% clinical benefit and 61% 1-year survival rate. This phase 3 ENGOT-ov50/GOG-329/INNOVATE-3 study [NCT03940196] investigates TTFields plus weekly paclitaxel in PROC patients.

Methodology Patients (N=540) will have PROC (RECIST V1.1) within 6 months of last platinum therapy with maximum of 2–5 prior lines of systemic therapy, ECOG 0–1 and no peripheral neuropathy >grade1. Patients with primary refractory disease will be excluded. Patients will be randomized 1:1 to weekly paclitaxel alone or weekly paclitaxel (starting of dose 80 mg/m2 weekly for 8 weeks, and then on Days 1, 8, and 15 for subsequent 28-day cycle) plus TTFields (200 kHz for 18 hours/day and continued if no progression in the abdominal or pelvic regions ('in-field region') per RECIST V1.1. Clinical follow-up will be performed q4w, with radiological follow-up (CT or MRI scans of the abdomen and chest) q8w. The primary endpoint is overall survival. Secondary endpoints: PFS, objective response rate, AEs, and quality of life (EORTC QLQ-C30 with QLQ-OV28). Sample size (n=540) will detect an increase in median OS from 12 to 16 months (HR 0.75). Data Monitoring Committee (DMC) meeting (March 2020) concluded that data to-date showed no safety issues and recommended trial continuation.

Results TiP N/A

Conclusion TiP N/A

Disclosures

554 BIOPSAR STUDY: ULTRASOUND-GUIDED PREOPERATIVE BIOPSY TO ASSESS HISTOLOGY OF SARCOMA-SUSPICIOUS UTERINE TUMORS. A NEW STUDY PROTOCOL

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Topic: Trials in progress abstract

Introduction/Backgroun The preoperative differential diagnosis between a uterine fibroma and a sarcoma is a challenge. Available diagnostic tools are rather inconclusive to distinguish between two pathologies. However, potential accurate diagnostic methods would be of great clinical impact in order to optimize surgical treatment.

Methodology A prospective multi-center interventional study will be performed. Ten tertiary French centers will participate in the present study. The overall inclusion study period will be 2 years, overall study duration will be 5 years. Patients greater than 35 years old, diagnosed with suspicious uterine tumor and needing surgical intervention will be included. Uterine tumors will be considered as suspicious in case of rapid tumor growth (≥30% of the maximum diameter in 1-year interval), symptomatic tumors in postmenopausal women, tumors characterized by certain suspicious ultrasound criteria history of treatment with tamoxifen and genetical predisposal to cancer syndromes. Included patients will undergo preoperatively a Vaginal Ultrasound-Guided Biopsy (VUGB). There will be two histopathological diagnoses for each patient, the first based on the biopsy specimen received preoperatively (Index test) and the second based on the surgical specimen of uterus resected 'en block'. These diagnoses will be compared in order to assess diagnostic performance of VUGB. Histological criteria used for both diagnoses will be that of Bell et al which were revised by OMS 2014 classification.

Results Our primary study hypothesis is that diagnostic performance of VUBG is capable to differentiate fibroma and sarcoma with a sensitivity greater than 90%. Considering as acceptable a sensitivity of 90% (H0) and excellent a sensitivity of 95% (H1), a sample size of 250 patients would be necessary to achieve 80% statistical power with a 5% type-1 statistical error. Taking into account a potential drop-out rate of 10%, there will needed 275 subjects to be included in our study. Primary study endpoint is sensitivity of VUGB anatomopathological diagnosis. Secondary endpoints include specificity, accuracy Youden's index, positive and negative predictive values.
Conclusion In case VUGB is demonstrated to be effective and safe to make the differential diagnosis, this should permit preoperatively the stratification of patients to either laparotomy for sarcomas or minimally invasive surgery for benign myomas. Therefore, both unnecessary laparotomies and cancer-spoilage by sarcoma morcellations could be avoided at the maximum degree.
Disclosures Authors have nothing to disclose

527 ANALYSIS OF UTERINE LAVAGE FOR EARLY OVARIAN CANCER DETECTION

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Introduction/Background Ovarian cancer (OC) has the highest mortality rate of all gynecologic. Currently there is no effective screening methodology or accurate early diagnostic test for OC. In recent years, it has been demonstrated that uterine lavage fluid could be useful for OC diagnosis and molecular profiling.
Methodology The aim of this study was to screen uterine lavage and ovarian tissue samples form Lithuanian OC patients for cancer-related mutations by targeted next generation sequencing (NGS) and to determine their associations with clinical features. DNA from 35 uterine lavage fluid from ovarian cancer, uterine cancer and benign ovarian mass patients and 20 ovarian tissue samples were analysed using NGS. The sequencing libraries were prepared using Ion AmpliSeq™ On-Demand Panel targeting 10 OC related genes: BRCA1, BRCA2, PIK3CA, PTEN, KRAS, TP53, CTNNB1, PPP2R1A, ARID1A and FBXW7. Variant uncertain significance (VUS) pathogenity predicted with VarSome database.
Results Technique of lavage from uterine cavity was successfully performed in all patients. We were able to detect 37 SNP (22 of these known to be pathogenic) in 20/35 uterine lavage samples, of these 19 (10 known pathogenic mutations) matched SNP found in tissue samples. 4/15 VUS predicted to be pathogenic: ARID1A c.5548delG, c.6628C>T, c.3606delG and BRCA1 c.3871delT. We were able to detect 62.5% (10/16) known pathogenic mutations in both matched samples (n = 17). Most mutations found in patients with serous OC and metastases.
Conclusion Cell-free DNA samples obtained from uterine lavage could be used for molecular profiling of OC patients. Uterine lavage is a simple procedure which can be performed in a physician's office-based setting and it holds great potential and significant promise for earlier diagnosis of OC and suggest the future possibility of this approach for screening women for gynecological cancers.
Disclosures This study is supported by NCI research fund.

Late breaking abstracts

Breast cancer

611 EFFECT OF SENTINEL LYMPH NODE BIOPSY ON UPPER LIMB FUNCTION IN WOMEN WITH EARLY BREAST CANCER: A SYSTEMATIC REVIEW OF CLINICAL TRIALS

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Introduction/Background Axillary surgery is essential in the management of early breast cancer. Conservative procedures like sentinel lymph node biopsy (SLNB) are less invasive than the traditional axillary dissection. However, some extent of ipsilateral upper limb dysfunction might still occur. The aim of this systematic review was to describe the incidence of lymphedema, pain, sensory, and motor disorders after SLNB in women with breast cancer.
Methodology We conducted a systematic review of randomized controlled trials. The search was performed on Pubmed, EMBASE, CINAHAL, and Web of Science. The search was based on the following concepts: breast cancer, sentinel lymph node biopsy, axillary dissection, upper limb complications. The risk of bias was evaluated using the Cochrane Rob 2.0 toll.
Conclusion SLNB is associated with postoperative complications that persist up to at least two years after the surgical procedure. The burden of complications, although lower when compared to axillary dissection, should not be ignored.
Disclosures The authors have no conflict of interest to disclose.

Cervical cancer

576 CLINICAL CHARACTERISTICS, TREATMENT RESPONSE AND PROGNOSIS OF LOCALLY ADVANCED ADENOCARCINOMA OF THE CERVIX, A LOCAL STUDY

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Introduction/Background Treatment of locally advanced cervical carcinoma regardless of histology, either, squamous, adeno- or adenosquamous carcinoma is the same, concurrent chemoradiotherapy. Nevertheless, studies have different and contradictory results regarding the impact of tumor histology in relation to treatment response. The current study sought to determine the clinical characteristics, treatment response and prognosis of locally advanced adenocarcinoma of the cervix in comparison to squamous cell carcinoma.
Methodology Records of the cervical cancer patients from the outpatient department of the Section of Gynecologic Oncology of a tertiary hospital were retrospectively reviewed.