PHASE 2 RESULTS FROM THE LIO-1 STUDY (NCT04042116; ENGOT-GYN3/AGO/LIO): EFFICACY AND SAFETY OF LUCITANIB + NIVOLUMAB IN PATIENTS WITH ADVANCED GYNAECOLOGICAL MALIGNANCIES

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Introduction/Background LIO-1 (NCT04042116) assesses the combination of lucitanib, an oral anti-angiogenic, multikinase inhibitor administered using safety-based dose titration, and nivolumab, an inhibitor of programmed cell death receptor 1 (PD-1). Here, we present phase 2 study results of this combination in 4 advanced gynaecological malignancies.

Methodology LIO-1 enrolled patients with advanced, recurrent or metastatic endometrial cancer (EC), cervical cancer (CC), high-grade ovarian cancer (OC) or EC/OC with clear-cell histology (EOCC). Patients with EC, CC or OC received ≥1 prior platinum-based chemotherapies (CC, ± bevacizumab; EOCC, + taxane); patients with OC received ≥2 prior chemotherapies (including ≥1 platinum doublet). Patients received lucitanib at a starting dose of 6 mg QD plus intravenous nivolumab 480 mg every 28 days. Lucitanib dose could be escalated to 8 mg then 10 mg QD. The data cutoff was 14 April 2022.

Results Total treated was 124 patients; 31 (25.0%) patients are ongoing. At data cutoff, 32 (25.8%) patients escalated to lucitanib 8 mg and 20 (16.1%) to 10 mg. The confirmed best overall response rates at data cutoff were: EC cohort, 5/22 (22.7%); CC cohort, 12/46 (26.1%); OC cohort, 4/33 (12.1%); EOCC cohort, 6/23 (26.1%). Among EC-cohort patients, confirmed responses were reported for 2/5 patients who received prior PD-1 inhibitor (both were non-responders to prior PD-1 inhibitor). Among EC-cohort patients with known microsatellite status, confirmed responses were observed in 3/14 with microsatellite stability and 2/3 with high instability. Grade ≥3 treatment-emergent adverse events (TEAEs) considered study-treatment related were reported in 55 (44.4%) patients, with the most frequent being hypertension (n=30 [22.7%]); TEAEs leading to lucitanib dose reduction or discontinuation occurred in 21 (16.9%) and 20 (16.1%) patients, respectively.

Conclusion Lucitanib + nivolumab displays anti-tumour activity in patients with advanced gynaecological malignancies, including clear-cell cancer. Effective dose titration resulted in manageable safety, similar to previous reports.

ANATOMY OF THE PRESACRAL REGION

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Introduction/Background The dissection of the presacral region is an integral component of multiple gynecologic cancer procedures such as lymph node staging, advanced staged disease and recurrence surgeries. The lack of knowledge of the anatomy can lead to severe complications such as vascular, ureteral, or nerve injuries that make up the complex region. To show anatomic concerns when surgeons dissect this region and to avoid severe complications we have developed a cadaveric video of the presacral region as well as the analysis and disposition of the more important anatomical landmarks.

Methodology We hereby demonstrate the anatomic data concerning the presacral region. Fifteen female cadaveric dissection models were evaluated. The presacral space was dissected to clearly defined anatomic landmarks. The midline of the region was marked from the promontory to its inferior edge, and measurements were taken from this imaginary line to key anatomical structures proximal to the presacral space. Special emphasis is placed on guiding the surgeon using still photographs and videos of cadaveric and live tissue dissection to optimize the understanding anatomy of the region.

Results The disposition of the following structures was analyzed in relation to the midline of the region; right ureter, right iliac vessels, left iliac vessels, specially left common iliac vein and hypogastric plexus. Additionally, middle sacral vessels were studied. The average distance between the midline of the region and right ureter was 3.1 cm, right common iliac vein 1.9 cm, right common iliac artery 2.6 cm, left common iliac vein 2.7 cm and left common iliac artery 3.4 cm. The location of the middle sacral vessels was quite variable.
Conclusion We highlight in this video the identification and systematization of the most important anatomical structures and landmarks located in the presacral region with the aim of achieving a safe dissection during gynecologic cancer procedures.

Abstract 2022-VA-445-ESGO Figure 1

Conclusion Primary squamous cell carcinoma of the breast is rare. The clinical and radiological aspects are not specific. Treatment is based on the surgical option. The prognosis remains controversial.

2022-RA-583-ESGO SQUAMOUS CELL CARCINOMA OF THE BREAST: 3 SPECIFIC CASES

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Introduction/Background Primary squamous cell carcinoma of the breast is a very rare malignancy of the breast, that represents only 0.1 to 2% of breast cancers.

Methodology This is a retrospective study of 3 patients treated for squamous cell carcinoma of the breast between 1995 and 2018, at the oncological radiotherapy department in the University Hospital Farhat Hached, Sousse.

Results When diagnosed, the patients were 36, 62, and 69. The reason for seeking consultation was a nodule in the left breast in the case of 2 patients and mastalgia in the right breast in the third. Mammography showed suspicious opacities, ranging from 15 to 34 mm, in the 3 patients with ipsilateral axillary adenopathy in 1 patient. A biopsy was performed and the anatomical pathology indicated breast SCC in the three patients. The extension assessment was negative. One patient underwent neoadjuvant chemotherapy, followed by an intervention of the type Patey. The other 2 were operated on immediately: lumpectomy-axillary dissection in one case and mastectomy axillary dissection in the other. Adjuvant chemotherapy was performed on these 2 patients. The anatomical pathology study showed a damaged lymph node in 2 patients, and the limits were healthy in 2 cases and permeated in the third. Hormone receptors were negative in 1 patient and unknown in the other 2. The 3 patients underwent radiotherapy at a dose of 52.2 Gy (1.8 Gy per fraction) with a boost of 14.4 Gy on the primary tumor bed area in 1 patient. The median follow-up was of approximately 10 years. One patient died from an array of pulmonary and cerebral metastases. The other two are being monitored and in complete remission.

Conclusion Primary squamous cell carcinoma of the breast is rare. The clinical and radiological aspects are not specific. Treatment is based on the surgical option. The prognosis remains controversial.

2022-RA-597-ESGO NEUROENDOCRINE CARCINOMA OF THE BREAST: A CASE REPORT

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Introduction/Background Primary neuroendocrine carcinoma of the breast is a rare histopathological variant. It represents 0.1% of breast cancers.

Methodology We report a case treated in the department of oncology-radiotherapy of Sousse with the aim of detecting the anatomoclinical, therapeutic and evolutionary aspects of this cancer.

Results We report the case of a 52-year-old patient. The history of her disease was marked by the appearance of a nodule of the left breast. An echo mammogram was performed and showed a 2.5 cm solid and irregular nodule in the inner quadrant of the left breast classified as ACR4. This nodule increased in size with the appearance of permeation nodules and bleeding with a new mammogram showing a large tumor in the left breast measuring 14 cm associated with carcinomatous mastitis and homolateral axillary adenopathies. The biopsy concluded to a poorly differentiated neuroendocrine carcinoma of the breast. Hormone receptors were positive, HER2 labeling was negative and Ki67 was evaluated at 80%. the tumor was classified as T4dN1M1a (costal involvement). The patient received 3 courses of FEC100 but due to clinical progression, a second line of VP16-cisplatin-based chemotherapy was indicated. The evolution was marked by an increase in tumor size with spontaneous bleeding. The patient underwent locoregional radiotherapy at a dose of 50Gy (2Gy per fraction) with a 20Gy boost on the tumor including the costal lesion followed by a left mastectomy. The evolution was marked by adrenal and cerebral progression 8 months after surgery. Given the refractory nature of chemotherapy, only hormone therapy was pursued. The patient underwent total brain irradiation radiotherapy at a dose of 20 Gy in 5 fractions with good tolerance.

Conclusion Primary neuroendocrine carcinoma of the breast is a rare entity with a poor prognosis. The literature has been limited to case reports in which the management has been similar to our case.