Stopping rules were formulated in order to monitor the groin recurrence rate.

Results: From December 2005 until October 2016, 1,708 patients were included in GROINSS-V II/GOG270. After exclusion of 156 ineligible patients, 1,552 patients were available for analysis. The SLN was negative in 1,222 patients (78.7%). During follow-up, 144/1,222 (11.8%) patients were diagnosed with local recurrence, of whom 16/144 (11%) also had groin metastasis. Isolated groin recurrences were diagnosed in 38/1,222 patients (3.1%). In 6/38 patients, clear protocol violations were observed: incomplete treatment of groin ($n = 3$); primary tumor >4 cm ($n = 1$); not all SNs visualized on the lymphoscintigram were removed ($n = 2$). Prognostic factors related to groin recurrences will be presented.

Conclusion: In the largest prospective series of SLN-negative vulvar cancer patients ever reported, the safety of omitting inguinofemoral lymphadenectomy after a negative SLN could be confirmed with a groin recurrence rate of 3.1% (after exclusion of the protocol violations 2.7%), comparable to the data of our first GROINSS-V study.

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LBA 3 - Scientific Plenary

Radiotherapy as an alternative treatment for inguinofemoral lymphadenectomy in vulvar cancer patients with a metastatic sentinel node: Results of GROINSS-V II

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Objective: In order to reduce treatment-related morbidity, the GROINSS-V II trial investigated whether radiotherapy is a safe alternative for inguinofemoral lymphadenectomy (IFL) in vulvar cancer patients with a metastatic sentinel node.

Method: GROINSS-V II was a prospective multicenter phase II trial, including patients with early-stage squamous cell carcinoma of the vulva (diameter <4 cm) without suspicious lymph nodes at imaging, who had primary surgical treatment with sentinel node procedure. In case of a metastatic sentinel node (metastasis of any size), radiotherapy was given to the groin (50 Gy). Stopping rules were defined to monitor groin recurrence rate.

Results: From December 2005 until October 2016, 1,708 patients were registered. Overall 1,552 patients were eligible, of whom 324 (21%) had a metastatic sentinel node. After 54 months of inclusion, the stopping rule was activated; interim analysis showed an increased risk for groin recurrence in case of sentinel node metastasis >2 mm and/or with extranodal extension (ENE). The protocol was amended, with patients only with micrometastasis ≤2 mm receiving radiotherapy from then on, and those >2 mm undergoing IFL (with radiotherapy if >1 metastasis or ENE). Final analysis after ≥2 years revealed 6 isolated groin recurrences in 157 patients with a sentinel node micrometastasis (3.2%). Four could not be considered radiotherapy failures: 2 developed recurrence in the contralateral (sentinel node-negative) groin; 2 refused radiotherapy. Twenty-eight patients did not undergo radiotherapy. Among 129 patients who received radiotherapy to the groin, 2 isolated groin recurrences were diagnosed (1.6%). Radiotherapy to the groin after sentinel node procedure showed only minimal toxicity: 5/118 (4.2%) had grade 3 toxicity, while no grade 4 or 5 toxicity was observed.

Conclusion: Radiotherapy to the groin is a safe alternative for IFL in patients with sentinel node metastasis ≤2 mm, with minimal toxicity. For patients with sentinel node metastasis >2 mm, radiotherapy with a total dose of 5 0Gy was no safe alternative for IFL; dose escalation and/or chemoradiation should be investigated in these patients.

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4 - Scientific Plenary

Phase II OVARIO study of niraparib + bevacizumab therapy in advanced ovarian cancer following front-line platinum-based chemotherapy with bevacizumab

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Objective: Niraparib improves progression-free survival (PFS) in newly diagnosed and recurrent ovarian cancer (OC) in patients after platinum-based chemotherapy in all biomarker-defined subgroups. OVARIO (NCT03326193) is a single-arm study evaluating niraparib + bevacizumab treatment in advanced OC after response to first-line platinum-based chemotherapy + bevacizumab.

Method: All patients with newly diagnosed FIGO stage IIIB–IV OC who had a complete or partial response (CR or PR) after first-line platinum-based chemotherapy + bevacizumab were eligible. Patients receiving neoadjuvant chemotherapy, as well as primary debulking surgery, were eligible. All patients underwent tissue testing for homologous recombination deficiency or proficiency (HRd or HRp) at enrollment. Bevacizumab dosage was 15 mg/kg every 3 weeks up to 15 months, including time on first-line chemotherapy. Niraparib, 300 or 200 mg once daily, based on baseline body weight and platelet count, was started within 12 weeks of completing first-line treatment and continued for 3 years or until progressive disease (PD) or unacceptable toxicity. The primary endpoint is PFS at 18 months from treatment initiation. An interim analysis of PFS at 6 months from treatment initiation was performed after all patients had had 2 scans after starting treatment.