Conclusion: Robot assisted laparoscopic staging surgery is feasible and safe with early ovarian cancer. Additionally, prospective randomized clinical trials will be able to evaluate the clinical benefits of robot-assisted surgery.

CHARACTERIZATION OF LONG-TERM SURVIVOR AND MAINTENANCE THERAPY IN RELAPSED OVARIAN CANCER (CAROLIN)-INTERGROUP STUDY NOGGO/A-AG0

Methodology

Trial design:

Long-term survivors (>5 years after primary diagnosis) with platinum-sensitive relapsed ovarian cancer (OC) constitute a rare, not well-investigated cohort among OC patients. The recent Expression IV study of the Northeast German Society of Gynaecologic Oncology (NOGGO) on patients' preferences and expectations regarding maintenance therapy has shown that patients primarily choose maintenance therapy to improve therapeutic outcome. Only secondarily do they opt for maintenance therapy to improve their quality of life (QoL). Furthermore, approximately 30% of patients prefer an oral administration and over 50% would tolerate a 2-year administration of maintenance therapy if the delay of tumor progression could exceed over six months. Based on these results, this prospective study characterizing the long-term experience of patients with OC undergoing maintenance treatment was planned. The objective of this trial is to prospectively evaluate the long-term survival multi-factorial experience in patients undergoing maintenance treatment. In particular, this study aims to identify disease, patient, and treatment factors associated with long-term survival.

Methodology

Trial design:

Enrollment of 300 patients with platinum-sensitive relapsed OC who are eligible for PARP inhibition in up to 15 sites in Germany and Austria. Treatment decision has to be determined independently by the physician before inclusion of the patients into the study. The niraparib treatment should be planned according to current SmPC. Patients can be included after therapy decision of Niraparib treatment (decision to start Niraparib therapy must have been taken independently) and for up to 3 months after start of Niraparib therapy. During this study data will be collected at baseline and every 3 months for up to 7 years follow-up (long-term survival with every 6 months visits) or patient’s death whatever comes first. Since 04/2021 13 patients with maintenance therapy were recruited within the study ‘CAROLIN’.

Results / Conclusion:

PROGNOSTIC IMPACT OF MOLECULAR Profiles and Molecular Signatures in Clear Cell Ovarian Cancer

Introduction/Background:

Ovarian Clear Cell Carcinomas (OCCC) are characterized by a low response to chemotherapy and a poor prognosis in advanced stages. Several studies have demonstrated that OCCC is not a uniform entity. Previously, we have identified four potential molecular subtypes based on the mutational status of ARID1A and PIK3CA. This study aimed to examine and describe the association between different molecular profiles, Tumor Mutational Burden (TMB), and molecular signatures with the clinical outcome in OCCC.

Methodology:

We identified 55 OCCC cases with corresponding data and biological tissue samples in the Danish Gynecological Cancer Database (DGCD) in the period January 2005 to December 2016. The mutational profiling and Tumor Mutational burden (TMB) were performed using the Oncmine Tumor Mutational Load Assay. Chi square and cox regression analyses were performed. P-values of <0.05 were considered statistically significant.

Results:

Mutations in the PIK3CA gene (p=0.04), as well as low TMB (p=0.05), were associated with the progression of the disease (yes vs no). In analyses adjusted for stage, patients with mutations in either ARID1A or PIK3CA were both associated with an impaired Progression Free Survival (PFS), and Overall Survival (OS) compared to cases who were wildtype for ARID1A and PIK3CA (undetermined subgroup) ((HR 5.42 and HR 2.77, respectively). High TMB status was associated with an improved PFS (HR 0.36) and OS (HR 0.46), although the latter only reached borderline significance. A trend toward an improved PFS in patients with APOBEC enrichment was observed (HR 0.45).

Conclusion:

We found that TMB-High is associated with decreased risk of progression and with an improved PFS and OS. Furthermore, a subgroup of OCCC with mutations in either the ARID1A and/or PIK3CA genes had a significantly impaired prognosis compared to the undetermined subgroup in analyses adjusted for stage.