Assessment of the prognostic impact of the published European Society of Gynecologic Oncology quality indicators for advanced ovarian cancer surgery -
Founding project of The ESGO Database
based on The ESGO Consortium of Accredited Centers

Investigators:

All participating ESGO accredited centers

(114 centers from 27 countries have confirmed interest in participation)

International project lead:

Prof. Nicole Concin, ESGO president

Ass. Prof. Ane Gerda Eriksson, Chair ESGO accreditation committee

Prof. Christoph Grimm, ESGO Task force ESGO European Database

Prof. Viola Heinzelmann, ESGO Task force ESGO European Database

ESGO Advisors:

Prof. Igance Vergote, ESGO Life-time award winner (2019)

Prof. Andreas du Bois, ESGO Life-time award winner (2021)

STUDY SYNOPSIS

Background:
Multiple studies have confirmed that centralization improves outcomes in women with advanced stage ovarian carcinoma (OC), in part due to complex treatment algorithms including extensive cytoreductive surgery. Therefore, the European Society of Gynaecological Oncology (ESGO) has established and published ten quality indicators for centers performing advanced ovarian cancer surgery. Based on these quality indicators, ESGO runs institutional accreditation processes for advanced ovarian cancer surgery in two categories, i.e. regular accreditation for advanced ovarian cancer surgery and centers of excellence for advanced ovarian cancer surgery. There are currently 72 such accredited centers in Europe and beyond. ESGO also runs institutional accreditation processes for endometrial cancer surgery and for training centers in gynaecological oncology. In total, there are 118 ESGO accredited centers. Of note, no large international multicenter study has validated the ESGO quality indicators of advanced ovarian cancer surgery as of yet.

Study design/objectives:
The present study is set out to assess the prognostic impact of the established ESGO quality indicators for advanced ovarian cancer surgery in a large international, multicenter study comprising ESGO accredited centers. All 118 ESGO accredited centers will be invited to participate in the present study. They will provide clinical data on the 10 ESGO quality indicators in ovarian cancer surgery and follow- up data on progression-free (PFS) and overall survival (OS) for the past three years, i.e. 2020, 2021, and 2022. Importantly, data will only be collected for patients who have initially presented at the respective center in Q1 and Q2 (6-month period) in these past three years. To avoid selection bias, the following two patient cohorts of Q1 and Q2 from the past three years (i.e. 2020, 2021, 2022) will be included into the present study 1) ALL consecutively incoming patients at the center with *newly diagnosed* advanced (stages III and IV) ovarian cancer (importantly, irrespective of whether they underwent surgery or not during their primary therapy), and 2) ALL *recurrent* OC patients who underwent secondary of tertiary cytoreductive surgery at the center (importantly, surgical cases only).
The primary objective of this study is to evaluate the prognostic impact of the ten ESGO quality indicators in advanced ovarian cancer surgery on PFS. Secondary objectives will comprise (not exclusively) association between the ten ESGO quality indicators and OS, and prognostic implication of center's accreditation status.

Conclusions:
The present study will evaluate the ten published ESGO quality indicators with respect to PFS and OS to assess their prognostic implication.

STUDY DESIGN and MAJOR INCLUSION CRITERIA

The present study is an international multicenter, retrospective cohort study based on the ESGO consortium of accredited centers.

The following patients treated at the participating ESGO accredited centers in **Q1 and Q2 (6-month period)** in the past three years, i.e. **2020, 2021 and 2022** will be included into the present study:

1) ALL consecutive incoming patients at the center with ***newly diagnosed*** **advanced stage (FIGO III and IV) ovarian cancer** (importantly, irrespective of whether they underwent surgery or not during their primary therapy), and
2) ALL ***recurrent*** **OC patients who underwent secondary or tertiary cytoreductive surgery at the center** (importantly, surgical cases only).

Participating centers will provide both, patient-level data (e.g. demographic, tumor-related, treatment-related and prognostic information per patient) and center-level data (e.g. infrastructure, processes in place). Data will be entered into a REDcap database maintained by ESGO.

ETHICAL, REGULATORY AND PRIVACY CONSIDERATIONS

All data collected from the patients' medical records during this study will be kept pseudonymized in accordance with Institutional policies and supervisory authority guidelines, Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the "**GDPR**"), as well as any national rules taken in particular on the basis of Article 9.4 of the GDPR relative to the processing of the personal data concerning health.

The study protocol will be reviewed by the Institutional Review Board (IRB)/ethics committee (EC) of each participating center. Data will not be entered into the ESGO REDCap database until IRB/EC approval is obtained. Each center will be responsible of obtaining its own IRB/EC approval.