2022-RA-1263-ESGO PHASE II RANDOMIZED BGOG-CX3 TRIAL COMPARING ATEZOLIZUMAB IN COMBINATION WITH DOXORUBICIN VERSUS DOXORUBICIN ALONE IN SECOND-LINE OR LATER RECURRENT CERVICAL CANCER

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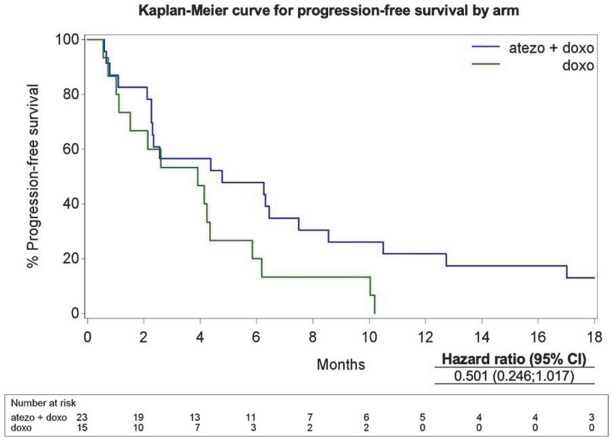
Introduction/Background Single-agent chemotherapies, like doxorubicin, have very modest activity in recurrent cervical cancer (rCC). Recently, anti-programmed-death protein 1 (anti-PD-1) treatment has shown activity in randomized phase III studies in rCC. In the current study we investigated the combination of doxorubicin with an anti-PD-L1 inhibitor atezolizumab (DA), based on the possible synergistic effect, versus doxorubicin (D) alone.

Methodology Prospective open-label, randomized phase II BGOG-cx3 trial (EudraCT2016–000547–14) randomizing 2:1 to doxorubicin (60 mg/m^2 q3 wks) with or without atezolizumab (1200 mg q3wks), respectively. The primary endpoint was progression-free survival (PFS) rate at 9 months. Secondary endpoints included objective response rate (ORR), duration of response (DOR), disease control rate (DCR), overall survival (OS), PFS and safety analysis.



Abstract 2022-RA-1263-ESGO Figure 1

Results 40 patients were randomized between November 2017 and October 2020: 23 vs 17 patients for DA and D, respectively. Baseline characteristics were similar in both arms (total population: squamous cell carcinoma 84%, prior radiochemotherapy 69%, prior anti-VEGF 61%, median prior lines of chemotherapy in advanced/recurrent setting was 1 with range 0–2). There was a tendency towards a longer median PFS of 4.8 and 3.9 months (figure 1) for DA and D, respectively with HR 0.501 (95%CI 0.246–1.017) (p= 0.0558). Similarly, the primary endpoint, PFS rate at 9 months, was numerically higher but failed to reach significance (26% vs 13% for DA and D, respectively (p=0.054)). Median OS was 10.3 and 7.8 months (p= 0.21) for DA and D, respectively. DCR at 24 weeks was 16% (DA)vs 0% (D) (p=0.279). Results according to PD-L1 staining will be presented. Discontinuation and dose reductions of D were similar in both groups. No new safety signals were noted for the combination of DA.

Conclusion Notwithstanding the limited samples size, this study showed a tendency towards a prolonged PFS and OS when doxorubicin was combined with atezolizumab compared with doxorubicin alone in rCC.

2022-RA-1265-ESGO PATTERNS OF RECURRENCE AND PROGNOSTIC FACTORS IN LOCALLY ADVANCED CERVICAL CANCER

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Introduction/Background LACC is made up of very different patients treated for decades the same. The prognosis is still not good, especially in those with para-aortic nodal involvement. Its stratification based on thrisk of para-aortic nodal involvement is necessary for better management and prognostic improvement. The clinical-pathological patterns and factors associated with recurrences allow us to predict the risk of these as well a adapt our diagnostic therapeutic and follow-up protocols.

Methodology Retrospective analysis of 196 patients treated with concurrent chemoradiotherapy limited to pelvis (CCRT-P) (n=160) and para-aortic extended field radiotherapy with pelvic chemoradiation (CCRT-P+PAO) (n=36) where the clinical-pathological patterns and factors associated with recurrences were analyzed. In addition, the impact of the local-regional control (LRC) and an added analysis of the patterns and clinical-pathological factors once patients with an inadequate LRC were excluded (n=141).

Results Recurrences in CCRT-P+PAO group were lower (p=0.73;0.10;0.6, for distant (DR), para-aortic (PAOR) and both (D+PAO-R) respectively . Median to recurrence of 4.6 and 7 months for local-regional recurrences (LRR), DR and PAOR in the CCRT-P, and 10 months for total recurrences in the CCRT-P+PAO group. OS in the CCRT-P group was higher (p=0.14). In the CCRT-P group, the presence of >1 pelvis node and the absence of LRC were independent prognostic factors for DR and D+PAO-R (HR 2.42, IC 95% [1.4–4.8], p=0.012 and HR 2.4, IC 95% [1.06–4], p=0.033), and for all types of recurrences respectively (HR 21.8, IC 95% [9.9–47]; HR 8.14, IC 95% [3.1–2.1]; HR 21.2, IC 95% [10.1–44] for DR, PAOR and D+PAO-R, with p<0.000 in all types). OS was lower in patients with CCRT-P with >1 pelvic node (p<0.000) and inadequate LRC (p=0.023). Recurrences and median to recurrence in CCRT-P and adequate LRC group (n=141) was 16.3%, and

29 and 30 months for RAD and RPAO. After multivariate analysis, in the CCRT-P and adequate LRC group, a tumor size of ≥4 cm was associated as an independent prognostic factor for DR (HR 2.7, IC 95% [1.04–7], p=0.032). OS was lower in patients with a tumor of ≥4 cm in this group (p=0.12).

Conclusion There are different patterns of recurrence in LACC between those treated with CCRT-P and CCRT-P +PAO, that allows us to provide for the risk of these and adapt our diagnostic-therapeutic and follow-upprotocols. LACC patients treated with CCRT-P have clinical-pathological factors associated with recurrences that allow us to provide for the risk of these as well as adapt our diagnostic-the rapeutic and follow-upprotocols.

2022-VA-1296-ESGO COELIO-SCHAUTA: LAPAROSCOPICALLY ASSISTED RADICAL VAGINAL HYSTERECTOMY IN EARLY-STAGE CERVICAL CANCER

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Introduction/Background Since the publication of the LACC trial results, the role of minimally invasive radical hysterectomy for cervical cancer has been questioned. However, it is likely that the lower survival rates shown in the minimally invasive surgery (MIS) arm, were not directly related to the MIS itself, but rather to technical procedures linked to laparoscopic and robotic-assisted approaches, such as the use of uterine manipulators or the opening of the vagina through the abdominal cavity.

Methodology Laparoscopically assisted radical vaginal hysterectomy (LARVH) or Coelio-Schauta combines lymph node staging and pelvic space creation by laparoscopy with radical hysterectomy including parametrium-paracolpium resection performed predominantly by vaginal approach, as reported by Schauta. This technique has shown oncological results and surgical complications comparable with those reported for the open surgery arm of the LACC trial. During LARVH, colpotomy and closure of the vagina are performed at the beginning of the radical hysterectomy, precluding manipulation of the tumor during the procedure.

Results We present a step-by-step video demonstration of the LARVH technique as it has been performed for more than 25 years at Hospital Clinic of Barcelona following surgical technique described by Dargent and Querleu.

Conclusion Coelio-Schauta is a minimally invasive technique that adheres to the oncologic principle of tumor containment. It should be included in prospective randomized trials to clarify the role of MIS in early-stage cervical cancer.

2022-RA-1301-ESGO THE IMPACT OF HOSPITAL SURGICAL VOLUME ON SURVIVAL IN EARLY-STAGE CERVICAL CANCER TREATED WITH RADICAL HYSTERECTOMY: A SUB-ANALYSIS OF THE SCCAN STUDY

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Introduction/Background The objective was to evaluate the impact of number of radical hysterectomies (RHs) performed per year in each center on disease-free survival (DFS) and overall survival (OS), from patients previously included in the SCCAN study.

Methodology International, multicenter, retrospective study. Patients with FIGO-2009-stage IB1-IIA1 cervical cancer who underwent RH, did not undergo neo-adjuvant chemotherapy and with pathologic negative lymph nodes, were included. Patients were treated in national referral centers for gynecologic oncology according to updated national/international guidelines. Optimal cut-offs for surgical volume were identified using an unadjusted Cox proportional hazard model with DFS as outcome and defined as the