

type of evidence (*in vitro*, *in vivo*, clinical trial, *etc.*). Subsequently, a clinical trial database (clinicaltrials.gov and WHO-ICTRP) search was performed to generate a list of registered trials in cervical cancer with drugs from our databases.

**Result(s)\*** We queried 534 drugs from our drug databases. Of these, 169 drugs had at least one relevant abstract or registered trial in cervical cancer. Ninety-three drugs had at least human data available with 52 drugs evaluated in registered trials. Forty-two drugs had at most *in vitro* data.

All 169 drugs were assessed for strength of scientific rationale, feasibility for integration in cervical cancer standard of care, evidence of radiosensitisation and an assessment of the availability of the drug for clinical trials. Out of these 169 drugs, we present 5 examples, *i.e.* nelfinavir, plerixafor, valproate with hydralazine, sonidegib and cetuximab (table 1) of potential candidates out of 39 that have been prioritised for further investigation.

**Conclusion\*** This study has identified potential candidates that are worth evaluating in cervical cancer. Although many drugs warrant additional preclinical and clinical investigation, we are exploring the possibility of conducting international collaborative multi-arm trials with one or several of these drugs.

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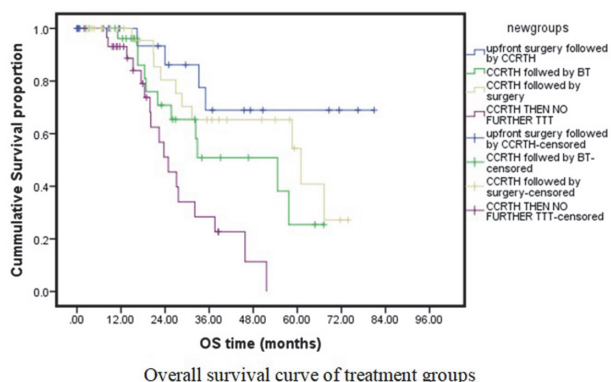
**OUTCOMES OF MANAGEMENT OF LOCALLY ADVANCED CERVICAL CANCER, NATIONAL CANCER INSTITUTE EXPERIENCE, CAIRO UNIVERSITY**

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**Introduction/Background\*** Cervical cancer is the 4th most common cancer affecting females with 85% of cases occurring in developing countries. There is limited data available in the literature about locally advanced cervical cancer management outcomes from Egypt. This is the first and the largest study to describe locally advanced cervical cancer treatment outcomes from Cairo University National Cancer Institute (NCI), the largest tertiary center for cancer in Egypt.

**Methodology** A retrospective study was conducted including 160 patients with pathologically proven cervical cancer, locally advanced disease (FIGO stage IIB till IVA) who presented to gynecology group, Radiation Oncology Department, NCI from 2013 to 2017. Data were collected retrospectively from patients' medical records. Demographic, clinicopathological,



**Abstract 148 Figure 1** Overall survival curve of treatment groups

treatment, and survival outcome data were retrieved. Survival analysis was estimated using the Kaplan-Meier method and compared using the log-rank test.

**Result(s)\*** Data analysis showed a great disparity in management plans. Local control (LC) was achieved in 65.1% of the patients, and 31% had metastatic disease progression. Non-compliance to treatment was seen in 18.8% of the patients. Three years overall survival (OS) and five years OS were 45.6% and 35% respectively. Non-compliant patients had significantly lower 3 years OS (28.4%,  $P < 0.001$ ). The most common modality of treatment was concurrent chemoradiation therapy (CCRTH) followed by radical surgery. There was no significant difference in OS, LC, and time to the distant metastasis between the different treatment modalities.

**Conclusion\*** Locally advanced cervical cancer management represents a challenging burden in developing countries like Egypt. Patient compliance was found to be the most important factor affecting survival in our population. Proper assessment of the factors causing low compliance should be properly evaluated. Strict follow-up and improving patient compliance are essential to achieve a favorable outcome.

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**PHASE 3 RECURRENT/METASTATIC CERVICAL CARCINOMA TRIAL: SUBGROUP EFFICACY ANALYSIS OF CEMIPIMAB VERSUS INDIVIDUAL INVESTIGATOR'S CHOICE CHEMOTHERAPY**

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**Introduction/Background\*** There is no standard of care regimen in the second-line setting for women with recurrent/metastatic (R/M) cervical carcinoma. Cemiplimab was recently shown to significantly improve overall survival (OS) compared with investigator's choice (IC) chemotherapy in patients with R/M cervical cancer after first-line platinum-based chemotherapy (NCT03257267; ESMO-VP-2021). We present a pre-planned exploratory subgroup analysis comparing cemiplimab to individual IC chemotherapy options.

**Methodology** EMPOWER-Cervical 1/GOG-3016/ENGOT-cx9 is an open-label, randomised (1:1), multi-centre, Phase 3 clinical trial of anti-programmed cell death (PD)-1 cemiplimab vs IC single agent chemotherapy in R/M cervical cancer that has progressed after first-line platinum-based treatment. The selection of single-agent chemotherapy by the investigator (gemcitabine, pemetrexed, vinorelbine, topotecan or irinotecan) was not protocol-defined, but the regimen had to be

Abstract 164 Table 1

Cemiplimab vs Individual IC chemotherapy	Investigator choice chemotherapy prior to randomisation				
	Pemetrexed (n=119 vs 111)	Topotecan (n=20 vs 21)	Irinotecan (n=26 vs 19)	Gemcitabine (n=108 vs 121)	Vinorelbine (n=31 vs 32)
Median OS	12.5 (7.5–15.3) vs 7.7 (6.4–9.8)  HR; 0.71 (0.52–0.98)	7.0 (3.9–15.0) vs 6.5 (4.4–8.8)  HR; 0.78 (0.31–1.96)	15.8 (11.2–NE) vs 11.8 (6.9–14.9)  HR; 0.69 (0.28–1.70)	10.7 (9.2–13.3) vs 9.0 (7.0–10.6)  HR; 0.76 (0.54–1.06)	10.3 (3.4–22.8) vs 7.6 (5.2–13.2)  HR; 0.77 (0.40–1.48)
Median PFS	3.0 (2.3–4.2) vs 2.9 (2.6–3.7)  HR; 0.70 (0.52–0.94)	2.2 (1.3–4.1) vs 2.3 (1.7–5.4)  HR; 0.90 (0.43–1.90)	6.9 (1.9–13.8) vs 4.2 (1.6–8.3)  HR; 0.77 (0.34–1.72)	2.8 (2.6–4.3) vs 2.8 (2.1–3.9)  HR; 0.73 (0.54–0.97)	1.5 (1.4–2.7) vs 2.8 (1.5–4.1)  HR; 1.21 (0.70–2.09)
ORR	16.0 (9.9–23.8) vs 6.3 (2.6–12.6)	15.0 (3.2–37.9) vs 4.8 (0.1–23.8)	23.1 (9.0–43.6) vs 15.8 (3.4–39.6)	17.6 (10.9–26.1) vs 5.0 (1.8–10.5)	9.7 (2.0–25.8) vs 6.3 (0.8–20.8)

Data shown by individual investigator choice of chemotherapy selected prior to randomisation in cemiplimab versus chemotherapy arms.  
OS and PFS data shown as months, 95% CI; ORR data shown as %, 95% CI.  
CI, confidence interval; HR, hazard ratio; NE, not evaluable.

chosen prior to randomisation. Adult females (age  $\geq 18$  years) were enrolled regardless of PD-ligand 1 expression and received cemiplimab 350 mg intravenously every 3 weeks or IC chemotherapy for up to 96 weeks; and were stratified by histology (squamous cell carcinoma/adenocarcinoma or adenosquamous), geographic region (North America/Asia/rest of world), prior bevacizumab, and ECOG performance status (0/1). Primary endpoint was OS. Additional endpoints included progression-free survival (PFS), objective response rate (ORR), duration of response, quality of life and safety. Data cutoff was 4 January 2021.

**Result(s)\*** A total of 608 patients were randomised: 304 to cemiplimab and 304 to IC chemotherapy (gemcitabine, n=121; pemetrexed, n=111; vinorelbine, n=32; topotecan, n=21; irinotecan, n=19) across geographic regions and histologies. Median duration of study follow-up (range) was 4.8 months (0.0–25.9) for the overall population. At second interim analysis, the trial was stopped early for efficacy. OS, PFS and ORR (table 1) demonstrated improvements with cemiplimab vs each IC chemotherapy treatment similar to those observed with cemiplimab vs pooled IC chemotherapy.

**Conclusion\*** Improvements in OS, PFS and ORR with cemiplimab trended consistently with the results for the overall population regardless of IC chemotherapy drug.

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#### DYNAMIC DOSE FRACTIONATION OF HDR-BRACHYTHERAPY AT PREOPERATIVE IRRADIATION OF CERVICAL CANCER PATIENTS

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**Introduction/Background\*** The direct influence of irradiation on cervical cancer can be realized by brachytherapy (BT). We have developed methodic of dynamic dose fractionation of brachytherapy, which determined the relevance of this investigation.

**The aim of this study** is efficacy improvement of combined treatment of cervical cancer patients, by application of high dose-rate brachytherapy (HDR) by the method of dynamic dose fractionation as a first step of preoperative course of radiochemotherapy.

**Methodology** There were enrolled 54 cervical cancer patients with primary stages IB – IIA (T1b-2aNxM0). All the patients were divided into 2 groups. BT was performed by device «MultiSource», and external beam radiation therapy (EBRT) – by «Clinac 600C», with chemomodification agent cisplatin 40 mg/m<sup>2</sup> weekly.

Group 1 included 34 patients, whose treatment was started with two sessions of BT (step 1) – the first one with single dose of 7 Gy, the second one – of 5 Gy, and then EBRT (20 Gy) up to the total dose of 32/23 Gy (step 2).

Group 2 included 20 patients, whose treatment was started with EBRT (20 Gy) – step 1, with sequential two sessions of BT with each single dose of 5 Gy (step 2), up to the total dose of 30/22.5 Gy.

The follow-up period was 3-26 months, mean – 17.2 months.

**Result(s)\*** The effectiveness of dynamic dose fractionation HDR-BT was proved by complete tumor regression (pathomorphosis grade IV) in 35.3% of 34 patients: 50.0% of stage IB patients and 36.4% – stage IIA. In group 2, there was detected only partial tumor regression (pathomorphosis of grade II-III) in all the patients. The relapsed disease was detected in 1 (6.7%) patient of Group 2 at follow-up before 1 year.