

Introduction/Background* Platinum-containing chemotherapy \pm bevacizumab is standard-of-care for recurrent/metastatic/persistent (R/M/P) cervical cancer (CC). Anti-PD-(L)1 therapy has benefit in some patients who progress after first-line (1L) therapy; 1L efficacy is unknown. HPV infection, implicated in >95% of CCs, is linked to TGF- β upregulation. Bintrafusp alfa is a first-in-class bifunctional fusion protein composed of the extracellular domain of the TGF- β RII receptor (a TGF- β 'trap') fused to a human IgG1 mAb blocking PD-L1. Promising activity was observed in patients with recurrent, platinum-experienced CC (response rate 28.2%). We report data from a phase 1b trial evaluating safety of 1L bintrafusp alfa + chemotherapy \pm bevacizumab (INTR@PID 046; NCT04551950).

Methodology Patients with R/M/P CC who had not received prior systemic therapy were eligible for cohort 1. They received bintrafusp alfa 2400mg q3w plus cisplatin 50mg/m² or carboplatin AUC5, paclitaxel 175mg/m² with (cohort 1A)/without (cohort 1B) bevacizumab 15mg/kg until disease progression, death, unacceptable toxicity, or withdrawal. Primary endpoints: occurrence of predefined dose-limiting toxicities (DLT) \leq 4 weeks from treatment start; adverse event occurrence. Target recruitment was 8 patients/cohort, with safety assessments when 3 and 8 patients had completed the DLT period.

Result(s)* As of May 4, 2021, 8 and 9 patients in cohorts 1A and 1B had received therapy for a median of 10.6 and 9.0 weeks. All patients had completed the DLT period and remained on therapy. Two non-bintrafusp alfa-related DLTs were observed in cohort 1B (grade 4 amylase elevation, grade 3 menorrhagia); neither led to treatment discontinuation. Any-grade treatment-related adverse events (TRAEs) occurred in 62.5% and 100% of patients in cohorts 1A and 1B. Grade 3 TRAEs occurred in 3 and 2 patients (cohort 1A: anemia [n=2], lipase increase, decreased neutrophil count, maculopapular rash [n=1 each]; cohort 1B: anemia, rectal hemorrhage, vaginal bleeding [n=1 each]); 1 patient in cohort 1B had grade 4 anemia. No treatment-related deaths occurred. Preliminary efficacy based on short follow-up showed 3 and 2 tumor responses (2 and 1 pending confirmation) in cohorts 1A and 1B.

Conclusion* No new safety signals were observed with 1L bintrafusp alfa + chemotherapy \pm bevacizumab in patients with R/M/P CC. Further studies are warranted.

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ULTRASOUND ROLE IN STAGING OF CANCER CERVIX

A Elagwany*. Alexandria university, Obg, Alexandria, Egypt

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Introduction/Background* Cancer cervix is common in developing countries due to limited adoption of screening programs. It is far less common in Developed countries due to availability of national screening program and governmental health insurance system. Cancer cervix in developing countries usually present in stage 1b and beyond. MRI and EUA is usually used for staging before surgery.

Methodology Recently, due to advanced technologies in ultrasound, we can now stage cancer cervix accurately and replace MRI and EUA. We are trying here to spot the lights over this with a pictorial illustration of different stages. The accuracy of vaginal sonography for the evaluating cancer cervix is

comparable to that of MRI and even better for local staging in identifying tissue planes

Result(s)* Ultrasound can be used in cancer cervix to assess the topography regarding exophytic versus endophytic tumor. The tumor size measured in three diameters and the distance between the tumor and the internal cervical os. the pericervical fascia which is the paracervix at the level of the cervix and the paracolpos at the level of the vagina is assessed. Thence, the extent of the radical procedure (parametrectomy) can be planned.

The tumor is usually hypoechoic in cases of squamous cell carcinoma and hyperechoic in adenocarcinoma. It is important in differentiating large bulky endocervical tumors (with regular outline) (stage 1) from those with parametrial invasion with irregular outline (stage 2 b). The vaginal extension is evaluated by the thickening or masses of the vaginal walls (stage 2a) along with assessing the paracolpos in the same manner as before (stage 2b). Ureteral dilatation is common in parametrial infiltration and is seen.

The spread into the urinary bladder and/or rectum (stage 4) can be determined and the ultrasound for the bladder involvement is better than does cystoscopy, as this can only show bullous mucosal edema or mucosal lesion but not the wall affection that can be seen by ultrasound. The assessment of both is based on assessing her muscle layer and the related fascia.

Conclusion* Ultrasound is comparable to mri in local staging of cancer cervix especially for minor changes.

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A LARGE, MULTICENTER, RETROSPECTIVE STUDY ON EFFICACY AND SAFETY OF STEREOTACTIC BODY RADIOTHERAPY IN OLIGOMETASTATIC CERVICAL CANCER (MITO-RT2/RAD)

¹G Macchia, ²M Campitelli, ¹P Bonome, ³C Laliscia, ⁴A Fodor, ⁵L Draghini, ⁶P Gentile, ⁷GR D'agostino, ⁸V Balcet, ⁹A Raguso, ¹⁰E Ippolito, ¹¹M Ferioli, ¹³L Vicenzi, ¹⁴S Borghesi, ²P Mitidieri, ¹⁵VDI Cataldo, ¹⁶E Perrucci, ¹⁷S Pignata, ¹⁸G Scambia, ¹⁹G Ferrandina*. ¹Gemelli Molise Hospital – Università Cattolica del Sacro Cuore, Radiation Oncology Unit, Campobasso, Italy; ²Fondazione Policlinico Universitario A. Gemelli, IRCCS, UOC di Radioterapia, Dipartimento di Scienze Radiologiche, Radioterapiche ed Ematologiche, Rome, Italy; ³University of Pisa, Department of Translational Medicine, Division of Radiation Oncology, Pisa, Italy; ⁴IRCCS San Raffaele Scientific Institute, Department of Radiation Oncology, Milan, Italy; ⁵S. Maria Hospital, Radiation Oncology Centre, Terni, Italy; ⁶UPMC Hillman Cancer Center San Pietro FBF, Radiation Oncology Unit, Rome, Italy; ⁷Humanitas Clinical and Research Hospital, IRCCS, Department of Radiotherapy and Radiosurgery, Rozzano, Italy; ⁸Nuovo Ospedale degli Infermi, UOC Radioterapia, Biella, Italy; ⁹Fondazione 'Casa Sollievo della Sofferenza', IRCCS, UOC Radioterapia, S. Giovanni Rotondo (FG); ¹⁰Campus Bio-Medico University, Department of Radiation Oncology, Rome, Italy; ¹¹Radiation Oncology, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna; ¹²Department of Experimental, Diagnostic and Specialty Medicine – DIMES, Alma Mater Studiorum University of Bologna; ¹³Azienda Ospedaliera Universitaria Ospedali Riuniti, Radiation Oncology Unit, Ancona, Italy; ¹⁴Azienda USL Toscana Sud Est, Radiation Oncology Unit of Arezzo-Valdarno, Arezzo, Italy; ¹⁵University of Florence, Radiation Oncology Unit, Oncology Department, Firenze, Italy; ¹⁶Perugia General Hospital, Italy, Radiation Oncology Section, Perugia, Italy; ¹⁷Istituto Nazionale Tumori di Napoli, Fondazione Pascale IRCCS, Naples, Italy; ¹⁸Fondazione Policlinico Universitario A. Gemelli, IRCCS, UOC Ginecologia Oncologica, Dipartimento per la salute della Donna e del Bambino e della Salute Pubblica, Roma, Italy; ¹⁹Fondazione Policlinico Universitario A. Gemelli, IRCCS, UOC Ginecologia Oncologica, Dipartimento per la salute della Donna e del Bambino e della Salute Pubblica, Roma, Italy

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Introduction/Background* Data supporting stereotactic body radiotherapy (SBRT) for oligometastatic gynecological cancer patients are increasing, but stereotactic treatments have not

yet been fully explored. The aim of this retrospective, multi-center study (MITO RT-02) was to define efficacy and safety of SBRT in a very large, real life dataset of metastatic/persistent/recurrent cervical cancer (MPR-CC) patients.

Abstract 933 Table 1 Patients and treatments characteristics

	N. (%)
Patients	84
Lesions	126
Age, yrs	58 (30-92)
Median (range)	
ECOG Performance Status	79 (94.1)
0-1	5 (5.9)
2-3	
Histotype	77 (61.1)
Squamous	36 (28.6)
Adenocarcinoma	5 (4.0)
Adenosquamous	3 (2.4)
Clear cell	5 (4.0)
Other	
N. lesions per patients	61 (72.6)
1	13 (15.4)
2	10 (12.0)
≥3	
Type of lesion (%)	70 (55.5)
Lymph node	46 (36.5)
Parenchyma	10 (8.0)
Bone	
Anatomic Site	7 (5.5)
Neck	34 (27.0)
Thorax	32 (25.4)
Abdomen	46 (36.6)
Pelvis	7 (5.5)
Bone	
Metachronous lesions	99 (78.6)
No	27 (21.4)
Yes	
N. patients undergoing previous radiotherapy in site	53 (63.1)
No	31 (36.9)
Yes	
Equipments	108 (85.7)
INAC	10 (7.9)
Cyberknife	1 (0.8)
Tomotherapy	7 (5.6)
MRI LINAC	
Type of treatment	26 (20.6)
SRS, stereotactic radiosurgery (single fraction)	100 (79.4)
SBRT, stereotactic radiotherapy (more fractions)	
PTV	16.8 (1.8-223.3)
Median, range (cc)	
Total dose, Gy	35 (5-60)
Median (range)	
Dose/fraction, Gy	7 (2.5-26)
Median (range)	
Dose prescription	48 (38.1)
Specific isodose	32 (25.4)
Isocenter	46 (36.5)
Target mean	

Methodology Clinical and SBRT parameters have been collected in order to fulfill primary endpoints, i.e. the rate of complete response (CR) to SBRT, and the 24-month actuarial local control (LC) rate on 'per lesion' basis. The secondary end-points were acute and late toxicities. Objective response rate (ORR) included CR and partial response (PR). Clinical benefit (CB) included ORR and stable disease (SD). Toxicity was evaluated by RTOG/EORTC and CTC-AE scales, according to center policy.

Result(s)* Fifteen centers participated to the study; after evaluation of inclusion/exclusion criteria, 84 CC patients, carrying a total of 126 lesions treated by SBRT between March 2006 and February 2021, were selected for the analysis. Patient characteristics and treatment data are summarized in **table 1**. Complete and partial response, as well as stable disease were observed in 73 (57.9%), 30 (23.8%), and 16 (12.7%) lesions, respectively, reaching about 94% CB rate. With a median follow-up of 14 months (range: 3-130), the 24-month actuarial LC, DFS and OS rate were 61.8%, 22.3%, 52.9%, respectively. Mild acute toxicity was experienced in 14 (16.6%) patients; late toxicity was documented in 4 patients (4.7%).

Conclusion* This study confirms the efficacy and safety of SBRT in MPR-CC patients. The low toxicity profile suggests a wider use of this treatment in this setting, however combinations with new drugs are needed to improve outcomes.

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ABSTRACT WITHDRAWN

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SURVIVAL AFTER RECURRENCE IN EARLY-STAGE CERVICAL CANCER PATIENTS

¹L Van Lonkhuijzen*, ²L Dostalek, ³J Jarkovsky, ⁴A Lopez, ⁵H Falconer, ⁶G Scambia, ⁷A Ayhan, ⁸S Kim, ⁹D Isla Ortiz, ¹⁰J Klat, ¹¹A Obermair, ¹²GDI Martino, ¹³R Pareja, ¹⁴R Manchanda, ¹⁵J Kostun, ¹⁶R Dos Reis, ¹⁷I Zapardiel, ¹⁸V Weinberger, ²D Cibula. ¹Amsterdam UMC, locatie AMC, Gynecologic oncology, Amsterdam, Netherlands; ²First Faculty of Medicine Charles University, Gynecologic Oncology Center, Department of Obstetrics and Gynecology, Prague, Czech Republic; ³Faculty of Medicine Masaryk University, Czech Republic; ⁴National Institute of Neoplastic Diseases, Gynecological Surgery; ⁵Karolinska University Hospital, Department of Pelvic Cancer, Stockholm, Sweden; ⁶Fondazione Policlinico Universitario A. Gemelli, Roma, Italy; ⁷Baskent University, Gynecology and Obstetrics, Division of Gynecologic Oncology, Ankara, Turkey; ⁸Memorial Sloan Kettering Cancer Center, Department of Surgery, New York, USA; ⁹National Institute of Cancerology Mexico, Gynecology Oncology Center, Mexico, Mexico; ¹⁰University of Ostrava – Faculty of Medicine, Obstetrics and Gynecology, Ostrava, Czech Republic; ¹¹The University of Queensland, Queensland Centre for Gynaecological Cancer, Saint Lucia, Australia; ¹²Building U6 – University of Milano-Bicocca, Department of Obstetrics and Gynecology, Gynaecologic Oncology Surgical Unit, Milano, Italy; ¹³National Cancer Institute – ESE, Department of Gynecologic Oncology, Bogotá, Colombia; ¹⁴Queen Mary University of London, Barts Cancer Centre, UK; ¹⁵University Hospital in Pilsen, Department of Gynaecology and Obstetrics, Prague, Czech Republic; ¹⁶The University of Texas MD Anderson Cancer Center, Department of Gynecologic Oncology and Reproductive Medicine, Houston, USA; ¹⁷La Paz University Hospital, Gynecologic Oncology Unit, Madrid, Spain; ¹⁸Faculty of Medicine Masaryk University, Brno, Czech Republic

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Introduction/Background* Up to 26% of early-stage cervical cancer patients relapse after primary surgical treatment. However, little is known about the factors affecting prognosis