Introduction/Background: Platinum-containing chemotherapy ± 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-βRII 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 ± 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) ≤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 aneuplyse 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 ± bevacizumab in patients with R/M/P CC. Further studies are warranted.
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.

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.

Abstracts

Abstract 933 Table 1 Patients and treatments characteristics

<table>
<thead>
<tr>
<th>N. (%)</th>
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<tbody>
<tr>
<td>Patients</td>
</tr>
<tr>
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</tr>
<tr>
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<td>ECOG Performance Status</td>
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Abstracts

937 ABSTRACT WITHDRAWN

942 SURVIVAL AFTER RECURRENTNESS IN EARLY-STAGE CERVICAL CANCER PATIENTS


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.