		N (%)
Age category (years)	≤40	54 (36.0%)
	41–60	78 (52.0%)
	>60	18 (12.0%)
Body mass index category (kg/mg²)	≤25	79 (52.7%)
	26–30	41 (27.3%)
	>30	30 (20.0%)
FIGO stage (preoperative)	IA1 + LVSI	10 (6.7%)
	IA2	12 (8.0%)
	IB1	128 (85.3%)
Tumor type	Squamous cell carcinoma	102 (68.0%)
	Adenocarcinoma	46 (30.7%)
	Adenosquamous carcinoma	2 (1.3%)
Tumor size (preoperative imaging)	≤2 cm	107 (71.3%)
	>2 cm	43 (28.7%)
Lymphovascular space invasion (LVSI)	Yes	40 (26.7%)
	No	110 (73.3%)
Surgical approach	Laparotomy	50 (33.3%)
	Minimally invasive	100 (66.7%)
Type of uterine procedure	Type B radical hysterectomy	36 (24.0%)
	Type C1 radical hysterectomy	61 (40.7%)
	Type C2 radical hysterectomy	24 (16.0%)
	Simple hysterectomy	1 (0.7%)
	FST (conization, trachelectomy)	28 (18.6%)
No of removed SLNs	2	59 (39.3%)
	3–4	69 (46.0%)
	>4	22 (14.9%)
SLN metastatic involvement	No	137 (91.3%)
	Macrometastasis or micrometastasis	9 (6.0%)
	Isolated tumor cells	4 (2.7%)
Adjuvant treatment	Chemoradiotherapy	12 (8.0%)
	Combined radiotherapy	5 (3.3%)
	Brachytherapy	1 (0.7%)
	None	132 (88%)

Abstract 114 Figure 2

Methodology In a prospective international multicenter trial SENTIX, the group of 150 patients with stage IA1–IB2 cervical cancer treated by uterine surgery with bilateral SLN biopsy was prospectively evaluated using both objective LLL assessments, based on limb volume increase (LVI) between pre- and postoperative measurements, and subjective patient-perceived swelling were conducted in six-month periods over 24-months post-surgery. The characteristics of the patients are summarized in table 1.

Result(s)* The cumulative incidence of LLL at 24 months was 17.3% for mild LLL (LVI 10-19%), 9.2% for moderate LLL (LVI 20-39%), while only one patient (0.7%) developed severe LLL (LVI >40%). The median interval to LLL onset was nine months (figure 1). A transient edema resolving without intervention within six months was reported in an additional 22% of patients. Subjective LLL was reported by 10.7% of patients, though only a weak and partial correlation between subjective-report and objective-LVI was found. No risk factor directly related to LLL development was identified.

Conclusion* Contrary to the expectations, the replacement of standard PLND by bilateral SLN biopsy in the surgical treatment of cervical cancer does not eliminate the risk of mild to moderate LLL, which develops irrespective of the number of SLN removed.

Trial registration ClinicalTrials.gov: NCT02494063

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Conflicts of Interest The authors declare no conflict of interest.

116 EVALUATION OF BINTRAFUSP ALFA, A BIFUNCTIONAL FUSION PROTEIN TARGETING TGF-β AND PD-L1, IN CERVICAL CANCER: DATA FROM PHASE 1 AND PHASE 2 STUDIES

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Introduction/Background* The accelerated US Food and Drug Administration approval of pembrolizumab validated the efficacy of anti-PD-(L)1 therapy for patients with recurrent/metastatic cervical cancer; however, the objective response rate (ORR) with pembrolizumab was 14.3% in patients with PD-L1–expressing tumours. Human papillomavirus infection is implicated in >95% of cervical cancers and is linked to

Abstract 116 Table 1

	All patients (N=39)
Best overall response, n (%)	2 (5.1)
Complete response (CR)	9 (23.1)
Partial response (PR)	3 (7.7)
Stable disease	20 (51.3)
Progressive disease (PD)	5 (12.8)
Not evaluable	1 (2.6)
Delayed PR*	
Confirmed ORR (CR + PR), n (%)	11 (28.2)
95% CI	15.0-44.9
Total clinical response rate (ORR + delayed PR), n (%)	12 (30.8)
Confirmed ORR in subgroups, n/n (%)	6/24 (25.0)
Squamous cell carcinoma	5/12 (41.7)
Adenocarcinoma	6/25 (24.0)
Prior bevacizumab	5/14 (35.7)
No prior bevcizumab	
Duration of response (confirmed ORR), median (range), months	11.7 (1.4-41.2)
Ongoing response, n/n (%)	5/11 (45.5)
Duration of ongoing response, months (range)	1.4-41.2
Median overall survival, months	13.4
95% CI	5.5-not reached
24-month overall survival rate,%	33.2

*Patient had a delayed PR after initial disease progression and did not meet response criteria by RECIST 1.1. Duration of response was 23.7 months.

upregulation of TGF-β signalling. 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 immunoglobulin G1 monoclonal antibody blocking PD-L1. We report pooled safety and efficacy in patients with pre-treated, immune checkpoint inhibitor-naive, recurrent/metastatic cervical cancer treated with bintrafusp alfa in phase 1 (INTR@PID 001; NCT02517398) and phase 2 (study 012; NCT03427411) studies.

Methodology Patients received bintrafusp alfa 0.3-30 mg/kg (phase 1 dose escalation) or 1200 mg every 2 weeks (phase 1 dose expansion and phase 2) until progressive disease, unacceptable toxicity, or withdrawal. Treatment past progression was allowed. Primary endpoints were safety (phase 1 dose escalation) and best overall response per RECIST 1.1 (phase 1 dose expansion and phase 2).

Result(s)* As of May 15, 2020 (phase 1) and December 22, 2020 (phase 2), 39 patients had received bintrafusp alfa for a median duration of 2.8 months (range, 0.5-19.3). The median follow-up to data cutoff was 35.0 months and 24.1 months for the phase 1 and phase 2 studies, respectively. All patients had received prior anticancer therapy; 16 (41.0%) had received ≥3 regimens. Confirmed ORR was 28.2% (table 1); responses occurred irrespective of Moore criteria (phase 1), tumour histology, prior bevacizumab treatment, or radiation treatment. Median overall survival was 13.4 months. No new safety signals and no treatment-related deaths were observed; side effects were manageable.

Conclusion* Bintrafusp alfa had a manageable safety profile and demonstrated clinical activity in patients with heavily pre-treated, immune checkpoint inhibitor-naive recurrent/metastatic cervical cancer.

117 SINGLE INSTITUTION OUTCOMES FOR CERVICAL CANCER PATIENTS TREATED RADICALLY WITH EBRT USING A PHASE 2 TECHNIQUE WHEN HDR BRACHYTHERAPY WAS NOT POSSIBLE

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Introduction/Background* To review overall survival (OS) and disease-free survival (DFS) for cervical cancer patients, unable to receive high dose rate brachytherapy (HDR BT), treated with external beam radiotherapy (EBRT) phase 2 boost

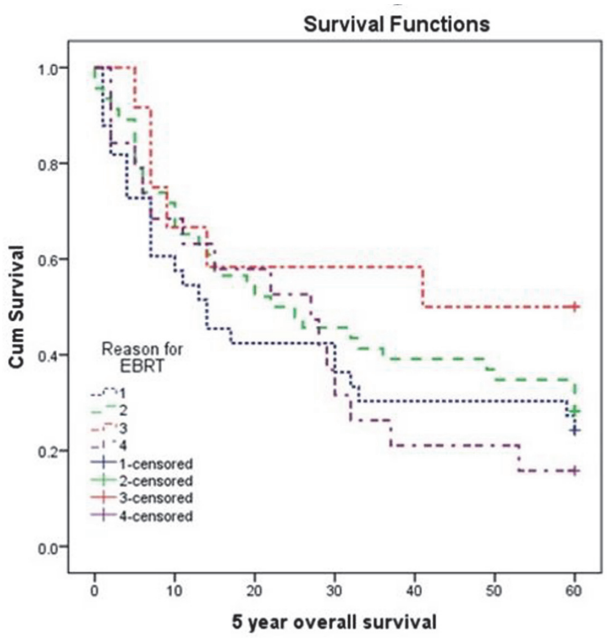
Methodology Data was retrospectively reviewed for patients treated with EBRT phase 2 boost for cervical cancer between 2011 and 2018. Staging, outcomes, recurrence rate and rationale for omitting HDR BT was recorded. The EBRT dose was 45Gy in 25 fractions to the pelvis +/- para-aortic area, followed by a phase 2 treatment of 20Gy in 10 fractions to residual primary disease. OS and DFS were calculated as a whole and for subgroups based on stage. The Kaplan-Meier method was used with log rank value to assess statistical significance, with two-tailed significance testing and with a p-value <0.05 deemed significant. All analysis was done using IBM SPSS statistical software version 24.

Result(s)* A total of 110 patients received a phase 2 boost over this 8 year period. The median age was 61 years (min 18 to max 87). The median radiotherapy dose was 64Gy (min 14Gy– max65Gy). Reasons for phase 2 include co morbidity (42%), technical limitations (30%), patient choice (11%) and poor compliance (17%).

The stage (FIGO 2009) distribution was: stage 1 (N=3), stage II (N=56), stage III (N=28) and stage IVA (N=23). The five-year DFS and OS for the entire cohort was 46% and 27% respectively. Analysing by stage the 5 year DFS for stage I was 33%, stage II was 46%, stage III was 50% and stage IVA was 43%. The 5 year OS for stage I was 33%, stage II was 34%, stage III was 25% and stage IVA was 13%. 5-year OS for reasons precluding HDR BT were technical limitations (24%), Co-morbidity (28%), patient choice (50%) and poor compliance (16%).

Abstract 117 Table 1

Number	Reason for EBRT	5-year OS
1	Tumour not amenable	24%
2	Co-morbidities/anaesthetic risk	28%
3	Patient Choice	50%
4	Other (Poor compliance)	16%



Abstract 117 Figure 1

Conclusion* This data demonstrates that OS and DFS for patients receiving EBRT phase 2 boost are inferior to those who receive HDR BT, irrespective of stage. It highlights the integral role of HDR BT in the treatment of cervical cancer and patients should be aware that omission can compromise outcome.