108 CLINICAL RELEVANCE OF ADDITION OF CONVENTIONAL TREATMENT TO CONCURRENT CHEMORADIOTHERAPY IN PATIENTS WITH FIGO STAGE III-IV CERVICAL CANCER

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Introduction/Background* Concurrent chemoradiotherapy (CCRT) has limited therapeutic efficacy for stage III-IV cervical cancer. We aimed to identify a subgroup of patients with stage III-IV cervical cancer who benefit from CCRT with additional treatment.

Methodology We retrospectively reviewed 120 patients with stage III-IV cervical cancer who were treated with CCRT from 2002 to 2018. We compared overall survival between patients treated with CCRT alone and those who received CCRT with additional conventional treatments (systemic chemotherapy before and/or after CCRT and/or extended-field radiation). Prognostic factors were statistically analyzed.

Result(s)* Overall, 44 (36.7%) and 21 (17.5%) patients were radiologically diagnosed with pelvic and para-aortic lymph node enlargement, respectively. The median tumor diameter was 5.7 cm. Sixty-nine (57.5%) patients received no additional treatment, and 51 (42.5%) received additional treatment. Cox regression analysis identified the following prognostic factors: histological non-squamous cell carcinoma (hazard ratio [HR], 3.9; 95% confidence interval [CI], 1.8–8.2), tumor diameter of $\geq$6 cm (HR, 2.1; 95% CI, 1.2–3.7), radiological pelvic lymph node enlargement (HR, 2.1; 95% CI, 1.1–4.0), and radiological para-aortic lymph node enlargement (HR, 2.1; 95% CI, 1.1–4.1). Even in the lowest risk group (no risk factors), the 5-year overall survival rate was lower in the additional treatment group than in the CCRT alone group (78.7% vs. 80.9%, respectively; log-rank test, $P = 0.79$).

Conclusion* Addition of conventional treatments to CCRT might not improve survival in patients with advanced cervical cancer. Novel treatment strategies including immune checkpoint inhibitors should be considered for such patients.

114 LOWER-LIMB LYMPHEDEMA AFTER SENTINEL LYMPH NODE BIOPSY IN CERVICAL CANCER PATIENTS

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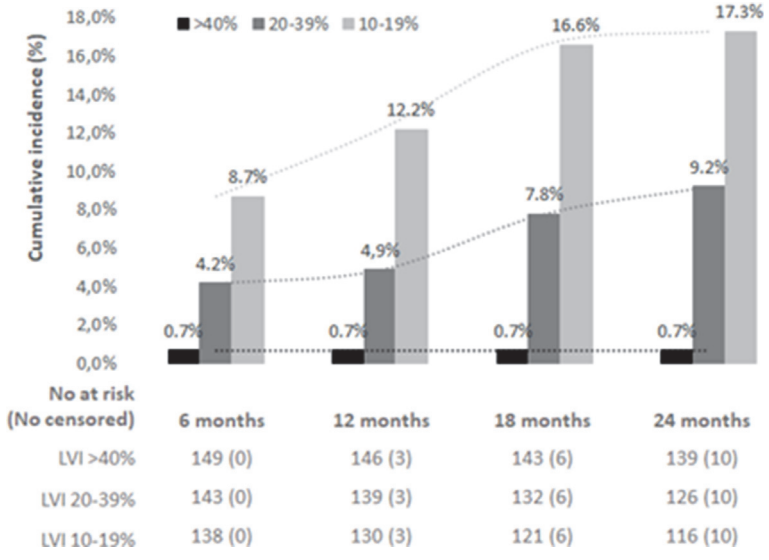
Introduction/Background* Lower-limb lymphedema (LLL) is a well-recognized adverse outcome of the surgical management of cervical cancer. Recently, sentinel lymph node (SLN) biopsy has emerged as an alternative procedure to systematic pelvic lymphadenectomy (PLND) aiming to decrease the risk of complications, especially LLL development. Our study represents the first prospective analysis of LLL incidence in cervical cancer patients after a uterine procedure with SLN biopsy, without systematic PLND.



Abstract 114 Figure 1

		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.