826 DOES THE MODE OF DELIVERY INFLUENCE THE NATURAL HISTORY OF UNTREATED CERVICAL INTRAEPITHELIAL NEOPLASIA?

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Introduction/Background* Abnormal cervical cytology has been reported in approximately 5% of pregnancies. Dynamic cervical changes produced during labor and vaginal delivery such as dilation, epithelial desquamation and immunologic/repair processes can be associated with higher regression rates of cervical intraepithelial (CIN) lesions. However, the published literature reveals heterogeneous data and controversial results about this effect.

The objective of this study is to evaluate the influence of the mode of delivery on the histologic regression, persistence and progression rates of CIN.

Methodology A retrospective cohort study including all patients who gave birth in Hospital del Mar (Barcelona, Spain) during 2015 and 2016 was performed, identifying patients with an abnormal cervical cytology previous to delivery. Subjects were required to have postpartum follow-up that included cervical cytology between 2-9 months postpartum.

The test used was liquid-based cytology and abnormal results were classified in atypical squamous cells of undetermined significance (ASCUS), low-grade squamous intraepithelial lesion (L-SIL), high-grade squamous intraepithelial lesion (H-SIL) and atypical glandular cells (ACG).

The evolution of lesions is evaluated according to whether regression, stability or progression occurs. Rates of regression and progression of cervical lesions according to the mode of delivery (vaginal vs cesarian section) were compared. Statistical analysis was performed by Chi-square test.

Result(s)* Data from 2586 pregnant women was revised, finding 197(7.6%) women with abnormal cytology, of which 122 women met inclusion criteria, 85(69.7%) delivered vaginally and 37(30.3%) by cesarean section. Regression occurred in 56 (65.9%) patients with vaginal delivery and in 28(75.7%) with cesarean section (p=0.395). Progression occured in 15 cases, 8(10.5%) delivered vaginally and 7(18.9%) by cesarean section (p=0.228).

The global regression rate was 69.2% for H-SIL, 63.5% for L-SIL and 75% for ASCUS. None of H-SIL progressed to invasive carcinoma and only one case of ACG resulted into H-SIL in postpartum.

Conclusion* In the group of patients studied, there are no differences in the rates of regression or progression of cervical lesions depending on whether they have a vaginal delivery or cesarean section.

This study reports a high regression rates and low progression rates after delivery supporting that a conservative management of CIN during pregnancy is safe.

947 RESULTS AFTER CONSERVATIVE SURGERY OF STAGE II/III SEROUS BORDERLINE OVARIAN TUMORS

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Introduction/Background* The aim of this study was to assess the outcomes of a large series of patients treated conservatively for a stage II or III serous borderline tumors of the ovary (SBOTs) with a long-term follow-up.

Methodology Patients with SBOTs and peritoneal implants, treated in or referred to our institution, were retrospectively reviewed. Outcomes of patients treated conservatively (preservation of the uterus and at least a part of one ovary) to promote subsequent fertility were specifically analyzed.

Result(s)* Between 1971 and 2017, 212 patients were identified and followed-up. Among them, 65 underwent a conservative treatment. Eight patients had invasive implants. Among patients treated conservatively, 38 (58%) patients recurred. Twenty-eight recurrences were observed under the form of borderline tumor on spared ovary and/or noninvasive implants, but 8 patients had a recurrence under the form of invasive disease. Compared to radical surgery, the use of a conservative treatment (p<.0001) was a prognostic factors on disease free survival (DFS), but without impact on overall survival (OS). Nevertheless, 3 deaths occurred. Twenty-four pregnancies (13 spontaneous) were observed in 20 patients (29 patients wishing to be pregnant).

Conclusion* In this series collecting the largest number of patients undergoing conservative surgery for stage II/III SBOTs, spontaneous pregnancies can be achieved after conservative treatment of advanced-stage disease, but the recurrence rate is high, and 3 deaths were observed. These patients spared their fertility but with a high rate of recurrence. Uncertainties about safety of conservative treatment should be exposed to them.

991 FERTILITY SPARING SURGERY IN CERVICAL CANCER PATIENTS OUTSIDE CONTROLLED TRIALS – A MULTICENTER RETROSPECTIVE COHORT TRIAL (CEEGOG CX-03; ENGOT-CX14)

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Introduction/Background* According to current guidelines fertility-sparing treatment (FST) in cervical cancer patients should follow the same principles as in patients without fertility

preservation. The literature from the last years, however, show a trend towards less-radical procedures. Although oncological outcomes are reported to be equal or better than in non-FST, published groups are small, mostly single institutional, inclusion criteria vary, and treatment is not uniform. The aim of this study was to collect retrospective data from multiple institutions across several countries on oncological and reproductive outcomes after FST.

Methodology Included were cervical cancer patients between 18–40 years with stages ≥ IA1+LVSI, who underwent any type of FST and completed follow-up of at least 6 months. Patients were eligible irrespective of neoadjuvant chemotherapy, histotype or tumour grade.

Result(s)* Altogether 733 patients from 44 centers in 13 countries were eligible for analyses. Median follow-up of the whole cohort was 6 years (1.2–14.5). More than half of the cases had stage IB1 (54.2%; 397/733). Mean age of patients was 32 years and two thirds were nulliparous (484/733). Most common surgical procedure was conization (48%). Repeated cervical surgery was performed in 161 patients (21.9%), most frequently re-conization (57.8%). Less than half of the patients (49.2%; 361/733) attempted to conceive after treatment. Out of them, 138 (38.2%) got pregnant and 100 (27.7%) successfully delivered. Pre-cancer recurrence was diagnosed in 22 (3%) patients, 51 (7%) patients had cancer recurrence and 19 (2.6%) died of disease. Three times higher risk of recurrence

Abstract 991 Table 1 Characteristics of cohort

	T1a1 L1 (N=208)	T1a2 (N=102)	T1b1 ≤2cm (N=356)	T1b >2cm (N=41)	T1b2 (N=19)	T2 (N=7)	p-value
Parity before diagnosis							
Nullipara	125 (60.1%)	66 (64.7%)	250 (70.2%)	24 (58.5%)	14 (73.7%)	5 (71.4%)	0.162
Primipara	54 (26.0%)	27 (26.5%)	82 (23.0%)	15 (36.6%)	4 (21.1%)	2 (28.6%)	
Multipara	29 (13.9%)	9 (8.8%)	24 (6.7%)	2 (4.9%)	1 (5.3%)	0 (0.0%)	
Age at first diagnosis of cervical cancer [years]							
mean (SD)	33.1 (4.7)	33.2 (4.4)	31.7 (4.5)	30.8 (3.4)	29.4 (5.1)	33.1 (5.2)	**<0.001**
median (5–95th percentile)	32.7 (25.9–40.8)	33.0 (27.4–40.0)	31.9 (24.4–39.3)	30.5 (26.2–36.5)	28.8 (19.3–38.8)	31.4 (27.0–42.8)	
Diagnostic procedure							
Biopsy	56 (26.9%)	23 (22.5%)	139 (39.0%)	24 (58.5%)	15 (78.9%)	5 (71.4%)	**<0.001**
Conization	131 (63.0%)	78 (76.5%)	212 (59.6%)	16 (39.0%)	3 (15.8%)	2 (28.6%)	
Pap smear	14 (6.7%)	1 (1.0%)	4 (1.1%)	1 (2.4%)	0 (0.0%)	0 (0.0%)	
Histological type							
Adenocancer	39 (18.8%)	25 (24.5%)	101 (28.4%)	9 (22.0%)	3 (15.8%)	1 (14.3%)	0.214
Adenosquamous	7 (3.4%)	4 (3.9%)	20 (5.6%)	1 (2.4%)	2 (10.5%)	0 (0.0%)	
Squamous	161 (77.4%)	73 (71.6%)	232 (65.2%)	30 (73.2%)	13 (68.4%)	6 (85.7%)	
Other	1 (0.5%)	0 (0.0%)	3 (0.8%)	0 (0.0%)	1 (5.3%)	0 (0.0%)	
Lymphovascular space invasion	**n=173**	**n=92**	**n=318**	**n=41**	**n=18**	**n=4**	
No	0 (0%)	69 (75.0%)	213 (67.0%)	25 (61.0%)	7 (38.9%)	1 (25.0%)	**<0.001**
Yes	173 (100%)	23 (25.0%)	105 (33.0%)	16 (39.0%)	11 (61.1%)	3 (75.0%)	
Neoadjuvant chemotherapy							
No	207 (99.5%)	102 (100.0%)	330 (92.7%)	34 (82.9%)	11 (57.9%)	2 (28.6%)	**<0.001**
Yes	1 (0.5%)	0 (0.0%)	26 (7.3%)	7 (17.1%)	8 (42.1%)	5 (71.4%)	
Type of surgical treatment							
Cervical procedure	208 (100.0%)	102 (100.0%)	356 (100.0%)	41 (100.0%)	19 (100.0%)	7 (100.0%)	-
Repeated cervical procedure	76 (36.5%)	20 (19.6%)	70 (19.7%)	4 (9.8%)	4 (21.1%)	0 (0.0%)	**<0.001**
Sentinel lymph node biopsy	55 (26.4%)	44 (43.1%)	171 (48.0%)	15 (36.6%)	9 (47.4%)	2 (28.6%)	**<0.001**
Pelvic lymphadenectomy	52 (25.0%)	81 (79.4%)	310 (87.1%)	32 (78.0%)	17 (89.5%)	5 (71.4%)	**<0.001**
Paraaortic lymphadenectomy	5 (2.4%)	1 (1.0%)	15 (4.2%)	0 (0.0%)	3 (15.8%)	0 (0.0%)	0.054
Cerclage placement	22 (10.6%)	26 (25.5%)	106 (29.8%)	13 (31.7%)	3 (15.8%)	1 (14.3%)	**<0.001**
Type of cervical procedure							
Conization	151 (72.6%)	54 (52.9%)	133 (37.4%)	5 (12.2%)	7 (36.8%)	2 (28.6%)	**<0.001**
Laparoscopic radical trachelectomy	1 (0.5%)	13 (12.7%)	30 (8.4%)	3 (7.3%)	0 (0.0%)	1 (14.3%)	
Radical abdominal trachelectomy	18 (8.7%)	17 (16.7%)	93 (26.1%)	21 (51.2%)	5 (26.3%)	3 (42.9%)	
Radical vaginal trachelectomy	18 (8.7%)	6 (5.9%)	67 (18.8%)	5 (12.2%)	3 (15.8%)	0 (0.0%)	
Robotic radical trachelectomy	1 (0.5%)	5 (4.9%)	6 (1.7%)	2 (4.9%)	1 (5.3%)	0 (0.0%)	
Simple vaginal trachelectomy	19 (9.1%)	7 (6.9%)	27 (7.6%)	5 (12.2%)	3 (15.8%)	1 (14.3%)	
Recurrence							
No	192 (92.3%)	96 (94.1%)	321 (90.2%)	33 (80.5%)	14 (73.7%)	7 (100.0%)	**0.028**
Yes	16 (7.7%)	6 (5.9%)	35 (9.8%)	8 (19.5%)	5 (26.3%)	0 (0.0%)	
Type of recurrence							
Pre-cancer	8 (3.8%)	5 (4.9%)	9 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.623
Invasive cancer	9 (4.3%)	2 (2.0%)	27 (7.6%)	8 (19.5%)	5 (26.3%)	0 (0.0%)	**<0.001**

Abstract 991 Table 2 Risk o recurrence (One-dimension logistic regression model)

	OR (95% CI)	p-value
Stage		
T1a1	Reference category	-
T1a2	0.442 (0.067–1.756)	0.302
T1b1 ≤2cm	1.815 (0.867–4.160)	0.132
T1b1 >2cm	5.360 (1.890–15.017)	**0.001**
T1b2	7.897 (2.188–26.316)	**0.001**
T2	-	-
Age at first diagnosis of cervical cancer [years]		
	0.956 (0.895–1.019)	0.175
Histological type		
Adeno	Reference category	-
Adenosquamous	1.228 (0.270–4.087)	0.759
Squamous	0.841 (0.440–1.696)	0.611
Other	19.038 (2.917–154.774)	**0.002**
Largest size of the tumor [mm]		
	1.057 (1.027–1.088)	**<0.001**
Type of cervical procedure		
Conization	Reference category	-
Laparoscopic radical trachelectomy	0.652 (0.102–2.315)	0.571
Radical abdominal trachelectomy	1.821 (0.927–3.524)	0.076
Radical vaginal trachelectomy	0.968 (0.348–2.318)	0.945
Robotic radical trachelectomy	-	-
Simple vaginal trachelectomy	1.034 (0.295–2.824)	0.952

was observed in tumours ≥ 2 cm in comparison to smaller tumours (19.4% vs. 5.7%; p<0.001). The most frequent locations of recurrence were cervix (53%) and pelvic nodes (22%). Median DFI for invasive recurrence reached 18 months.

Conclusion* Data from the real life practice showed that FST in cervical cancer patients is safe in patients with HPV related tumours smaller than 2 cm. In such tumours conization represents sufficient procedure with satisfactory pregnancy outcomes. Surprisingly less than half of patients attempt to conceive after treatment.

Miscellaneous

55 SGNTUC-019: PHASE 2 BASKET STUDY OF TUCATINIB AND TRASTUZUMAB IN SOLID TUMORS WITH HER2 ALTERATIONS: UTERINE AND CERVICAL CANCER COHORTS

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Introduction/Background* Tucatinib, a highly selective HER2-directed tyrosine kinase inhibitor with minimal EGFR inhibition, is approved for use in combination with trastuzumab and capecitabine in patients with breast cancer who have received anti-HER2–based regimens in the metastatic setting. In xenograft models of HER2-overexpressed/amplified (HER2+) and HER2-mutated tumors, dual targeting with tucatinib and trastuzumab showed superior activity to either agent alone.

The prognosis of locally-advanced unresectable or metastatic (LAUM) cervical and uterine cancer remains poor. HER2 amplification/overexpression and mutations occur in up to 21% and 80% of cervical and uterine cancers, respectively.

Methodology SGNTUC-019 (NCT04579380) is an open-label, international Phase 2 basket study evaluating tucatinib and trastuzumab in adult patients with LAUM HER2+ or HER2-mutated solid tumors. Multiple disease- and HER2 alteration-specific cohorts are being enrolled, including HER2+ cervical and uterine cancer cohorts. Patients will receive tucatinib 300 mg orally twice daily and trastuzumab 8 mg/kg IV on Cycle 1 Day 1 and 6 mg/kg q21 days from Cycle 2 Day 1

HER2+ cervical and uterine cancer cohorts will enroll 12 patients each. If ≥2 responses are observed in a cohort, it will be expanded to 30 patients. Patients with HER2-mutated cervical and uterine cancers will enroll in a cohort of 30 patients for all solid tumor types.

Eligible patients must have progressed on or after the last systemic therapy, with platinum-based therapy ± bevacizumab required in patients with metastatic cervical cancer. Patients must have ECOG PS ≤1, adequate organ function, and have not received HER2-directed therapy; patients with uterine serous carcinoma may have received trastuzumab. HER2 alterations can be demonstrated by HER2 overexpression/amplification in tumor tissue by prior IHC/ISH, or by HER2 amplification/mutation in a prior or on-study NGS assay of ctDNA or prior tissue NGS assay.

The primary endpoint is confirmed ORR per investigator. Disease control rate, duration of response, PFS, and OS are the secondary endpoints. Disease assessments per RECIST 1.1 will occur q6 weeks for 24 weeks, then q12 weeks. QoL will be evaluated q2 cycles using EQ-5D-5L.

Result(s)* Not applicable.

Conclusion* Enrollment in US began in Dec 2020; EU and Asia sites will be opened.

69 SURGICAL AND MEDICAL TREATMENTS FOR UTERINE PECOMAS

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Introduction/Background* Perivascular epitheliod cell tumors (PEComas) are rare mesenchymal neoplasms. Uterine PEComa is extremely rare and only limited evidence is still available.

Methodology This is a single-center retrospective study. Charts of consecutive patients who had treatment (from 01/01/2010 to 12/31/2020) for newly diagnosed uterine PEComas were retrieved. Five-year survival outcomes were assessed using Kaplan-Meier and Cox proportional hazard models.

Result(s)* Data of 23 patients with newly diagnosed PEComas were analyzed. Mean (SD) patients' age was 52 (14) years. Twenty-two patients had a surgical cytoreductive attempt. In one case surgery was not performed due to the presence of an extra-abdominal spread. Overall, seven (30%) patients had disease outside the uterus at the time of surgery. Complete cytoreduction (no macroscopic residual tumor) was achieved in 19 patients. Complete cytoreduction was not completed in