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

three patients who gross extrauterine disease and in the aforementioned patient who had not surgery. Eleven (48%) patients had adjuvant treatments, consisting in anthracycline-based chemotherapy (n=4),gemcitabine-based chemotherapy (n=2), mTOR inhibitors (n=4) and hormonal treatment (n=1). Median (range) follow-up as 23 (2, 99) months. Eleven (48%) recurrences occurred with a mean (SD) progression free-survival of 14 (11) months. After a median (range) follow-up of 23 (2, 99) months, nine (39%) patients died of disease. Residual tumor at surgery was the only factor correlating with the risk of developing recurrent disease (p=0.023) and worse overall survival (p=0.014). In our small series, stage of disease and adjuvant therapy administration had no impact on survival outcomes.

Conclusion* Uterine PEComa represents a rare and aggressive entity. Molecular/genomic profiling of the disease is necessary to predict response to treatment. Further collaborative investigations are warranted to assess the role of various prognostic factors and evaluate the most effective surgical and medical treatment modalities.

142 LOW PREOPERATIVE SKELETAL MUSCLE DENSITY PREDICTS POSTOPERATIVE COMPLICATIONS AND FUNCTIONAL DECLINE IN OLDER WOMEN WITH OVARIAN CANCER

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Introduction/Background* Insights in how to select older patients who can benefit from standard care and patients that need adjusted treatment are necessary. This study aims to determine the predictive value of lumbar skeletal muscle mass and density, measured on a computed tomography (CT) scan, for postoperative outcomes in older women with advanced stage ovarian cancer.

Methodology A multicentre, retrospective cohort study was performed in women ≥70 years old with advanced stage ovarian cancer who underwent surgery. Skeletal muscle mass and density were assessed in axial CT slices on level L3. Low skeletal muscle mass was defined as skeletal muscle index <38.50 cm^2/m^2. Low skeletal muscle density was defined as one standard deviation below the mean (muscle attenuation <22.55 Hounsfield Units). The primary outcome was any postoperative complication ≤30 days after surgery. Secondary outcomes included severe complications, infections, delirium, prolonged hospital stay, discharge destination, discontinuation of adjuvant chemotherapy and mortality.

To investigate whether skeletal muscle density was of added value as a predictor for postoperative complications, we first built a model with pre-existing relevant preoperative predictors only. After this model was built, we added skeletal muscle density to assess if it improved the model. A statistically significant step Chi-square statistic demonstrated that the new model performed better than the model with existing predictors.

Abstract 142 Table 1 Results from univariable and multivariable analysis of predictors used to build the multivariable predictable model for postoperative complications within 30 Days after surgery

Potential Predictors	Odds ratio	95% confidence interval	*p*-value	Odds ratio	95% confidence interval	*p*-value
	Univariable analysis			Multivariable analysis (n=178)		
Low skeletal muscle density*	2.83	1.41-5.67	**0.003**	2.57	1.21-5.45	**0.01**
KATZ-ADL ≥2 (n=178)	3.11	1.05-9.20	**0.04**	2.67	0.88-8.12	0.08
Candidate predictors associated with postoperative complications (*p* <0.20), but not improving the model						
Bowel surgery (n=210)	1.92	0.90-4.12	0.09			
FIGO stage IV	1.61	0.87-2.99	0.13			
Charlson Comorbidity Index ≥2	0.61	0.32-1.18	0.14			
Polypharmacy†	1.55	0.85-2.82	0.15			
Candidate predictors not associated with postoperative complications (*p* ≥0.20)						
Living at home with help (n=210)	1.62	0.72-3.65	0.24			
Undifferentiated tumor (n=195)	4.67	0.30-73.38	0.27			
Use of walking aid (n=178)	1.52	0.66-3.49	0.32			
Risk for malnutrition (n=117)	1.42	0.65-3.08	0.38			
ASA score 3‡ (n=211)	1.50	0.58-3.87	0.40			
Body Mass Index	1.03	0.96-1.09	0.46			
History of confusion during illness (n=181)	1.43	0.31-6.58	0.65			
Fall risk (n=173)	1.21	0.51-2.87	0.66			
Age	0.99	0.92-1.06	0.72			
Pre-existing memory problems (n=181)	0.79	0.20-3.18	0.74			

ASA = American Society of Anesthesiologists; FIGO = International Federation of Gynecology and Obstetrics; KATZ-ADL = Six-item Katz Index on independence in Activities in Daily Living.
Boldface data are statistically significant. If a variable has missing values, the number presented behind a variable represents the number of patients included in this analysis.

* Low skeletal muscle density is defined as a mean Muscle Attenuation (MA) <22.55 HU.
† Polypharmacy was defined as the daily use of ≥5 different medicines.
‡ The ASA classification (measured before surgery) ranges for 1 to 6, with higher scores indicating a worse physiological status and a higher operative risk.

Result(s)* 213 Patients were included. Preoperative low skeletal muscle density was associated with postoperative complications ≤30 days after surgery (Odds Ratio (OR) 2.83; 95% Confidence Interval (CI) 1.41-5.67), severe complications (OR 3.01; 95%CI 1.09-8.33), infectious complications (OR 2.79; 95%CI 1.30-5.99) and discharge to a care facility (OR 3.04; 95%CI 1.16-7.93). Preoperative low skeletal muscle mass was only associated with infectious complications (OR 2.32; 95% CI 1.09-4.92). In a multivariable model (table 1), low skeletal muscle density was of added predictive value for postoperative complications to the strongest existing predictor functional impairment (KATZ-ADL ≥2) (OR 2.57; 95%CI 1.21-5.45; step Chi-Square statistic p=0.01).

Conclusion* Low skeletal muscle density, as a proxy of muscle quality, is associated with worse postoperative outcomes in older patients with advanced stage ovarian cancer. These findings can contribute to preoperative risk assessment and clinical decision making.

147 USEFULNESS OF HYSTEROSCOPY IN THE MANAGEMENT OF BREAST CANCER PATIENTS WITH TAMOXIFEN AS AN ADJUVANT TREATMENT

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