

distortions, impaired sexual function, decreased quality of life and increased vulvar cancer risk.

An agreement to measure VLS severity in a standard way is yet to be defined and, to our knowledge, no standardized clinical classification of anatomical modifications in VLS has been validated.

The purpose of this study was to prepare a clinical classification for VLS aimed at defining the morphological patterns of this condition, while stratifying them into grades. The classification is intended to provide a homogeneous and reproducible description of the different features of this disease. It

also serves as an important tool for the evaluation of the course of the disease over time, response to treatment, and for comparison of clinical studies.

**Methodology** A board of seven specialists with expertise in vulvar pathology were asked to outline the anatomical criteria for the definition of VLS severity (phimosis of the clitoris, resorption of the labia minora, involvement of the inter-labial sulcus, and narrowing of the vulvar introitus), identifying five grades to be used to build-up of a score model. The classification was validated by 13 physicians upon pictures of 137 consecutive patients. Each physician individually assigned a grade to each case, according to the abovementioned criteria. Inter-rater agreement among evaluators was analysed by means of ICC (Intraclass Correlation Coefficient). Intra-observer reproducibility and inter-observer concordance in vivo were analysed by means of Kappa index.






**Results** This study provides a new classification of VLS, based on defined anatomical criteria and graded into mutually exclusive progressive classes (table 1).

The ICC analysis showed a substantial agreement in the attribution of the grade of VLS among the 137 cases, ICC=0,89 (0.87–0.91), both in the expert and in the non-expert group (ICC=0.92 and 0.87 respectively). An ‘almost perfect’ agreement was achieved for intra-observer reproducibility and among physicians in vivo (Kappa 0.93).

**Conclusion** Our classification showed a high accuracy in defining morphological modifications in VLS. It is easy to use, reproducible, and can be applied by different health care providers in daily clinical practice and in all clinical settings.

**Disclosure** Nothing to disclose.

**Abstract 310 Table 1** Clinical classification of vulvar lichen sclerosus

Grade	Description	Example
<b>Grade 1A*</b> <b>Minimal VLS</b>	- normal vulvar anatomy	
<b>Grade 2A*</b> <b>Mild VLS</b>	- partial phimosis of the clitoris - partial resorption of one or both labia minora - partial involvement of one or both inter-labial sulci	
<b>Grade 3A*</b> <b>Moderate VLS</b>	- total phimosis of the clitoris - total resorption of one or both labia minora - total involvement of one or both inter-labial sulci	
<b>Grade 4A*</b> <b>Severe VLS</b>	- presence of all grade 3 criteria** - narrowing of the vulvar introitus < 2 cm	
<b>Grade 5A*</b> <b>Extremely Severe VLS</b>	- narrowing of the vulvar introitus < 1 cm - urethral meatus unexposed	

*In the event of the coexistence of anatomical criteria corresponding to different grades, the case is attributed the grade which accords to the worst criterion.*

*\* 1B/2B/3B/4B/5B in presence of perianal involvement.*

*\*\* Defined as compresence of total clitoral phimosis, total resorption of one or both labia minora, total involvement of one or both inter-labial sulci.*

### 311 DIAGNOSTIC VALUE OF HE4, CA-125, ROMA AND CPH-I FOR PREOPERATIVE ASSESSMENT OF OVARIAN TUMORS

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**Introduction/Background** Among patients with adnexal masses, preoperative identification of epithelial ovarian cancer (EOC) or metastatic cancer in the ovary (MCO) is essential for surgical planning. Our aim was to assess the performance of CA125, HE4, and the probability models, Risk of Ovarian Malignancy Algorithm (ROMA) and Copenhagen Index (CPH-I), to preoperatively identify EOC or MCO.

**Methodology** We performed a single center retrospective study including women who underwent surgery for an ovarian tumor between January 2000 and December 2018. We defined two study groups: one group comprising women with benign pathology and borderline epithelial ovarian tumors and a second group comprising women with EOC or MCO. We computed sensitivity, specificity and predictive values of CA125, HE4, ROMA and CPH-I at different cutoff points. We performed receiver operative curve analysis for tumor markers, CPH-I and ROMA models. We performed subgroup analysis including only premenopausal, postmenopausal women, stage I EOC and women harboring ovarian tumors with inconclusive diagnosis of malignancy by ultrasound features.

**Results** One thousand seventy-one patients were included, 852 (79.55%) presented benign or borderline epithelial

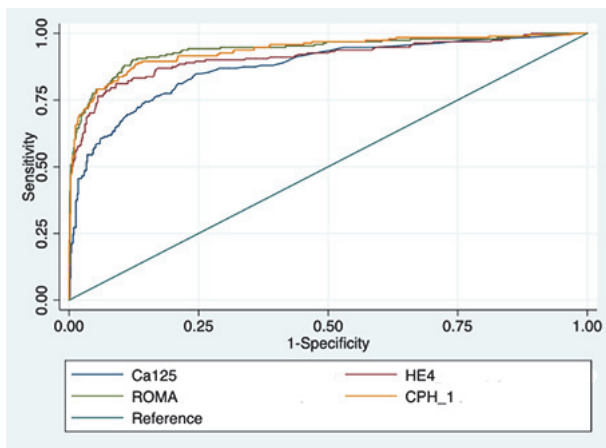
**Abstract 310 Table 2** Level of agreement among the raters

Agreement among the raters for the 137 cases of VLS				
	ICC	95% CI		
Total panel	0.89	0.87-0.91		
<b>Board members</b>	<b>0.92</b>	<b>0.89-0.93</b>		
Gynecologists with no expertise	0.87	0.84-0.90		
Cases in women aged < 50 years	0.92	0.86-0.96		
Cases in women aged > 50 years	0.89	0.86-0.92		
Agreement among the raters between the first and the second evaluation.				
	Board member 1	Board member 2	Gynecologist no expertise 1	Gynecologist no expertise 2
<b>Kappa (95% CI)</b>	0.91 (0.79-1.00)	0.96 (0.87-1.00)	0.79 (0.60-0.95)	0.91 (0.79-1.00)
<b>ICC (95% CI)</b>	0.97 (0.94-0.99)	0.99 (0.97-0.99)	0.93 (0.86-0.97)	0.97 (0.94-0.99)

**Abstract 311 Table 1** Sensitivity, specificity, and predictive values of Ca125, He4, ROMA index and CPH-1 index at different cutoff points

Parameter (cutoff)	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Ca125 (100 U/mL)	61.86 (55.21 - 68.09)	92.71 (90.73 - 94.29)	68.91 (62.07-75.02)	90.30 (88.11 - 92.11)
Ca125 (35/65 U/mL)*	74.42 (68.23 - 79.81)	80.70 (77.81 - 83.24)	50.21 (44.73 - 55.64)	92.30 (90.22 - 94.12)
Ca125 (35/100 U/mL)*	66.98 (60.44 - 72.92)	81.39 (78.58 - 83.90)	48.48 (42.86 - 54.15)	90.41 (88.07 - 92.32)
He4 (70 pmol/L)	83.25 (77.31 - 87.88)	86.11 (83.40 - 88.43)	61.15 (55.11 - 66.87)	95.14 (93.22 - 96.53)
He4 (120 pmol/L)	69.11 (62.23 - 75.23)	96.29 (94.65 - 97.44)	83.02 (76.42 - 88.06)	92.23 (90.10 - 93.93)
He4 (70/140 pmol/L)*	70.70 (63.93 - 76.71)	93.5 (91.52 - 95.11)	74.2 (67.40 - 80.01)	92.4 (90.20 - 94.10)
ROMA (10)	94.24 (89.98-96.75)	72.71 (69.27- 75.91)	47.91 (43.84 - 54.01)	97.85 (96.19 - 98.80)
ROMA (15)	91.10 (86.21 - 94.37)	84.62 (81.73-87.12)	62.14 (56.33-67.62))	97.17 (95.51 - 98.22)
ROMA (12.5/14.4)*	91.62 (86.83-94.78)	82.58 (79.57-85.23)	59.32 (53.63 - 64.77)	97.26 (95.60 - 98.31)
ROMA (13.1/27.7)*	84.8 (79.00 - 89.20)	89.0 (86.40 - 91.10)	68.1 (61.90-73.70)	95.5 (93.60 - 96.80)
CPH (1)	96.86 (93.32 - 98.55)	47.97 (44.26 - 51.70)	34.01 (30.15 - 38.09)	98.22 (96.17 - 99.18)
CPH (3)	91.10 (86.22 - 94.42)	79.12 (75.91 - 82.01)	54.72 (49.23 - 60.14)	97.01 (95.21 - 98.12)
CPH (5)	86.91 (81.39 - 90.97)	87.54 (84.86 - 89.79)	65.87 (59.82 - 71.45)	96.03 (94.20 - 97.29)
CPH (7)	82.20 (76.16 - 86.97)	90.87 (88.49-92.80)	71.36 (65.06 - 76.93)	94.86 (92.90-96.309)

PPV: positive predictive value; NPV: negative predictive value;  
\*premenopausal/postmenopausal women

**Abstract 311 Figure 1** AUC of He4, Ca125, ROMA and CPH-I. All patients

tumors and 219 (20.45%) presented EOC or MCO. Area under the curve (AUC) for HE4 was significantly higher than AUC for CA125 (0.909 vs 0.873). No differences were seen between AUC of ROMA (0.939) and CPH-I (0.936), but they were both higher than HE4 AUC (figure 1). Subgroup analysis showed that in premenopausal women, HE4 performed better than CA125, and was equivalent to ROMA or CPH-I. Considering only ovarian tumors with inconclusive diagnosis by ultrasound, ROMA performed better than CPH-I. None of the tumor markers alone achieved a sensitivity of 90%, however HE4 was highly specific (93.5%). ROMA showed a sensitivity and specificity of 91.1% and 84.6% respectively, while CPH-I showed a sensitivity of 91.1% with 79.2% specificity (table 1).

**Conclusion** Both ROMA and CPH-I were more favorable than tumor markers alone for differentiating patients harboring EOC or MCO. Probability models can be helpful in order to assess the risk of malignancy of ovarian tumors, especially when expert ultrasound examination is not available or when the diagnosis by ultrasound remains inconclusive.

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### ONE-STEP NUCLEIC ACID AMPLIFICATION (OSNA): A BIG 'STEP' TOWARDS A MORE ACCURATE INTRA-OPERATIVE ASSESSMENT OF SENTINEL LYMPH NODE STATUS FOR EARLY STAGE ENDOMETRIAL AND CERVICAL CANCER?

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**Introduction/Background** Sentinel lymph node (SLN) mapping is established as the standard of care for staging in selected cases of melanoma, breast and vulval cancer amongst other malignancies. Nonetheless, adapting its use in endometrial cancer (EC) and cervical cancer (CC) has been challenging. There is currently growing evidence to support its accuracy in early-stage EC and CC. One-step nucleic acid amplification (OSNA) has emerged as a rapid molecular assay for the detection of cytokeratin 19-mRNA in SLNs. The aim of the study was to ascertain the accuracy of OSNA in detecting SLN metastasis in early-stage EC and CC compared to that of histopathological ultra-staging.

**Methodology** A systematic search of MEDLINE, SCOPUS, ClinicalTrials.gov, and Cochrane Database was performed, spanning the period Jan 1975 to July 2020. Studies pertaining to the use of OSNA in detecting SLN metastasis in EC and CC were located. Pathologic ultra-staging was the reference standard. The quality of the included studies was assessed using the QUADAS-2 tool. The DerSimonian-Laird random-effects model was used. Sensitivity, specificity, positive and negative likelihood ratio (LR+/LR-), diagnostic odds ratio (DOR), and the area under the curve (AUC) on SROC curve were calculated. We assessed the inter-study heterogeneity by the Higgin's I2 index. Statistical analysis was performed using the STATA version 16.1.