

University of the Philippines - Philippine General Hospital. A preliminary analysis comparing OVERA and other strategies for malignancy risk prediction was performed.

**Results** As of this report, 347 women have been enrolled in the study. Based on sonologic classifiers, high risk patients had higher predictive scores using LR1 ( $\chi^2[2]$ : 260.81,  $p < 0.01$ ), LR2 ( $\chi^2[2]$ : 271.57,  $p < 0.01$ ), Sassone ( $\chi^2[2]$ : 127.26,  $p < 0.01$ ), Lerner ( $\chi^2[2]$ : 153.98,  $p < 0.01$ ), IOTA-ADNEX ( $\chi^2[2]$ : 215.22,  $p < 0.01$ ), and ROMA ( $\chi^2[2]$ : 144.48,  $p < 0.01$ ). Based on categorical classifiers, CA-125 ( $\chi^2$ : 34.59,  $p < 0.01$ ), OVERA ( $\chi^2$ : 54.25,  $p < 0.01$ ), and ROMA ( $\chi^2$ : 85.29,  $p < 0.01$ ) discerned well in the high-risk group, while HE4 ( $\chi^2$ : 105.10,  $p < 0.01$ ) discerned lower risk better. OVERA as a numerical variable appears to fare well in detecting the likelihood of malignant tumors ( $\chi^2[4]$ : 3.38,  $p$ : 0.50) as compared to sonologic models but was not as discerning as other models using the conventional cut-off value (5.0). A higher cut-off (6.9) would confer more optimal values of specificity across age (pre-menopausal or menopausal) and histopathologic types.

**Conclusion** The preliminary results stress the importance of population based studies in evaluating biochemical assays for ovarian cancer risk prediction.

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### ABDOMINAL RADICAL TRACHELECTOMY VERSUS CHEMOTHERAPY FOLLOWED BY VAGINAL RADICAL TRACHELECTOMY IN STAGE 1B2 (FIGO 2018) CERVICAL CANCER. A SYSTEMATIC REVIEW ON FERTILITY AND RECURRENCE RATES

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**Introduction** There is currently no standard of care for women with cervical cancer stage IB2 (FIGO 2019, diameter 2–4 cm) who wish to preserve their fertility. Generally, two approaches are offered. Option 1: neoadjuvant platinum-based chemotherapy (NACT) to reduce the tumor size to  $\leq 2$  cm, followed by Vaginal Radical Trachelectomy (VRT) with Pelvic Lymph Node Dissection (PLND) either before chemotherapy or at the time of VRT. Option 2: Abdominal Radical Trachelectomy (ART) with PLND.

**Objective** To compare rates of fertility, pregnancy, life births as well as recurrence for women with cervical cancer stage IB2 treated with either NACT followed by VRT, or ART.

**Methods** A systematic review was performed using the PubMed database. Articles reporting the search term ‘trachelectomy’ as text word or as Medical Subject Headings (MeSH) were identified.

**Results** Ten studies were identified with a total of 338 patients. After NACT followed by VRT 39% of the women tried to conceive, 70% of these women got pregnant, of which 63% resulted in a life birth. The overall recurrence and death rate were 10% and 2.9% respectively. After ART 40% of the women tried to conceive, 21% of these women got pregnant, which resulted in a life birth rate of 42%. Recurrence and death rate after ART were 6.9%, and 3.4% respectively.

**Conclusion** Women with cervical cancer stage IB2 and a wish to preserve fertility treated with NACT followed by VRT have a significantly higher chance of pregnancy than women treated with ART, with comparative oncological results.

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### ENGOT-CX11/GOG 3047/KEYNOTE-A18: A PHASE 3, RANDOMIZED, DOUBLE-BLIND STUDY OF PEMBROLIZUMAB WITH CHEMORADIO THERAPY IN PATIENTS WITH HIGH-RISK LOCALLY ADVANCED CERVICAL CANCER

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**Background** High-risk locally advanced cervical cancer (CC) has a poor prognosis, and >50% of patients recur in 2 years. Concurrent chemoradiotherapy (CRT) may enhance the immunostimulatory activity of the PD-1 inhibitor pembrolizumab. After KEYNOTE-158, in which pembrolizumab demonstrated durable antitumor activity, pembrolizumab monotherapy was approved for patients with PD-L1–positive recurrent or metastatic CC who progressed during or after chemotherapy. ENGOT-cx11/KEYNOTE-A18 (NCT04221945) is a phase 3, randomized, placebo-controlled study evaluating pembrolizumab with concurrent CRT in locally advanced CC.

**Trial design** Approximately 980 patients with high-risk, locally advanced, histologically confirmed CC who have not received systemic therapy, immunotherapy, definitive surgery, or radiation will be randomized 1:1 to receive 5 cycles of pembrolizumab 200 mg Q3W + CRT (5 cycles [with optional 6th cycle] of cisplatin 40 mg/m<sup>2</sup> Q1W + external beam radiotherapy [EBRT] followed by brachytherapy) followed by 15 cycles of pembrolizumab 400 mg Q6W or 5 cycles of placebo Q3W + CRT followed by 15 cycles of placebo Q6W. Randomization is stratified by planned EBRT type, cancer stage at screening, and planned total radiotherapy dose. Treatment will continue until patient receives  $\leq 20$  cycles of pembrolizumab (5 cycles 200 mg Q3W, 15 cycles 400 mg Q6W) vs placebo ( $\sim 2$  years) or until disease progression, unacceptable toxicity, or withdrawal. Primary endpoints are PFS per RECIST v1.1 by blinded independent central review and OS. Secondary endpoints include PFS at 2 years, OS at 3 years, complete response at 12 weeks, ORR, PFS and OS in PD-L1–positive patients, and safety. Enrollment is ongoing.