

with MTIT (24.1% vs. 60.7%, $P = 0.005$). Wound breakdown was the most common complication in our cohort, which occurred less frequently in the M-MTIT group than in the MTIT group (10.3% vs. 35.7%, $P = 0.022$). Multivariate logistic regression analysis identified M-MTIT as an independent predictor of reduced risk of wound breakdown. The incidence of other complications, including lymphedema, wound infection and cellulitis was lower in M-MTIT group than in MTIT group; however, the differences did not reach statistical significance. Median follow-up time of this study was 33 months. The Kaplan-Meier survival graphs did not show significant differences in recurrence-free survival and overall survival between the two groups.

Conclusions M-MTIT correlates with lower morbidity rates and does not compromise oncological safety compared with MTIT. It could be considered as a safe and feasible option for vulvar cancer patients with locally advanced disease.

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322 PREVALENCE OF HRHPV DNA AND P16/KI67 EXPRESSION AMONG WOMEN WITH CERVICAL DYSPLASIA

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Objectives Markers such as HPV DNA, p16 and ki67 are helpful to decide who among the screen positives require further management and treatment. So, this study was planned to estimate the prevalence of HPV DNA, p16 and Ki67 expression among the women with cervical dysplasia and to correlate high risk HPV DNA positivity and P16/Ki67 expression among them.

Methods In this hospital-based cross-sectional study, 146 women with abnormal Pap smear reports were included in the study and were subjected to HPV DNA testing and colposcopy and directed biopsy for histopathology and immuno-histochemistry for p16 and ki67. Women who have already received treatment for dysplasia and women who were pregnant were excluded from the study.

Results Totally 146 women with abnormal Pap report with a mean age of 47.8 years were studied. The prevalence of high-risk HPV was 44.5% and HPV 16, 56 and 18 were the common genotypes. The prevalence of P16 and Ki67 expression more than 5% was 20.5% and 34.3% respectively. Positive correlation was noted between high risk HPV and P16/Ki67 expression (p value of 0.0189 for P16 expression and HPV positivity, p value of 0.0027 for Ki67 expression and HPV positivity).

Conclusions The prevalence of high-risk HPV in our study population comprising of women with abnormal Pap smears was 44.5%. Positive correlation was noted between HPV, histopathology and P16 and Ki67 suggesting that these markers can be used as adjuncts in inconclusive cases during histopathological examination.

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323 ENGOT-EN9/LEAP-001: A PHASE 3 STUDY OF FIRST-LINE PEMBROLIZUMAB PLUS LENVATINIB COMPARED WITH CHEMOTHERAPY IN ADVANCED OR RECURRENT ENDOMETRIAL CANCER

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Background Prognosis and OS are poor in patients with advanced or recurrent endometrial cancer (EC). First-line standard of care for these patients is paclitaxel-carboplatin chemotherapy; however, more effective and tolerable therapies are needed. In the phase 1b/2 trial KEYNOTE-146, which assessed the PD-1 inhibitor pembrolizumab combined with the multikinase inhibitor lenvatinib, an ORR of 38% was observed in patients with previously treated advanced EC. ENGOT-en9/LEAP-001 (NCT03884101) is a randomized, open-label, active-controlled, phase 3 study investigating pembrolizumab + lenvatinib vs chemotherapy in patients with EC.

Trial design Patients with newly diagnosed advanced (stage III-IV) or recurrent EC not previously treated with antiangiogenic agents; systemic chemotherapy (unless within a chemoradiation regimen); PD-1, PD-L1, or PD-L2 inhibitors; or other T-cell receptor-targeted therapies will be eligible. Patients will be randomized 1:1 to receive pembrolizumab 200 mg Q3W + lenvatinib 20 mg daily or paclitaxel 175 mg/m² Q3W + carboplatin AUC 6 Q3W. Randomization will be stratified by proficient vs deficient mismatch repair (pMMR vs dMMR) status. The pMMR population will be further stratified by prior chemoradiation (yes/no), measurable disease (yes/no), and ECOG performance status (0/1). Patients will receive treatment for ≤35 cycles of pembrolizumab vs 7 cycles of chemotherapy or until initiation of a new anticancer treatment, unacceptable AEs, or withdrawal of consent. Primary endpoints are PFS (per RECIST v1.1 by blinded independent central review) and OS. Secondary endpoints are ORR, health-related QOL, safety/tolerability, and lenvatinib pharmacokinetics. Exploratory endpoints are disease control rate, clinical benefit rate, and duration of response. Enrollment is ongoing.

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324 THE COMPLEXITY OF DECISION-MAKING FOR RISK-REDUCING SURGERY IN WOMEN WITH LYNCH SYNDROME

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Introduction Risk-reducing surgery (RRS) in Lynch Syndrome effectively prevents endometrial and ovarian cancers.