THE UTILITY OF BIOMARKERS FOR OVARIAN CANCER RISK ASSESSMENT IN PRIMARY CARE: A PILOT STUDY

Introduction/Background

Ovarian cancer is the leading cause of mortality from gynaecological malignancy. Survival improves with early diagnosis, however, early detection in primary care is challenging. The current blood test, cancer antigen 125 (CA125), has limited sensitivity and specificity for early disease. Human Epididymis 4 (HE4) is a promising diagnostic biomarker. We aimed to investigate the diagnostic accuracy and clinical utility of serum HE4 in a symptomatic primary care population.

Methodology

We conducted a prospective observational study testing HE4 on primary care serum CA125 samples from women with suspected ovarian cancer in Manchester, UK, between April 2018 and April 2019. Serum HE4 was measured using chemiluminescent enzyme immunoassays following routine CA125 testing for clinical care. HE4 thresholds of 77pmol/L and 150pmol/L were used. The primary outcome was final diagnosis within 12 months of testing. Clinical outcomes were collected from hospital electronic patient records. Receiver operator characteristic (ROC) curves with area under the curve (AUC), sensitivity and specificity were calculated for CA125 and HE4 both alone and in combination. Age adjusted HE4 thresholds were calculated with linear regression models.

Result(s)

1,247 patients were included, with a mean age of 50 years (SD 15.7). 100 women had epithelial ovarian cancer, including 82 invasive and 18 borderline ovarian tumours. There was little difference in overall performance of CA125 and HE4 (AUC 0.932 vs 0.914 respectively). At a threshold of 77pmol/L, HE4 alone had a better sensitivity than CA125 [89% (95%CI 81.2-94.4) vs 81% (95% CI 71.9-88.2)] but a worse specificity [75.6% (95%CI 73-78) vs 92.2% (95% CI 90.4-93.6)]. HE4 and CA125 combined had improved sensitivity compared with CA125 alone (93%, 95%CI 86.1-97.1), but at a significant cost to specificity (70%, 95%CI 67.3-72.6). Serum HE4 levels were correlated with increasing age (p <0.001) and worsening eGFR (p<0.001). Age adjusted HE4 cut-offs marginally improved the specificity of CA125, however the numbers were small per age category and require validation in larger cohorts.

Conclusion

HE4 adds little to current diagnostic pathways in primary care. Age-adjusted thresholds may improve accuracy, but not sufficiently to recommend routine use at present.

433 MYOMETRIAL INFILTRATION ASSESSMENT IN LOW-RISK ENDOMETRIAL CANCER BY 3D TRANSVAGINAL ULTRASOUND AND DIFFUSION-WEIGHTED MAGNETIC RESONANCE IMAGING

Introduction/Background

In patients with early-stage, grade 1-2, endometrioid endometrial cancer, preoperative assessment of myometrial invasion is essential to define the need of pelvic and paraaortic lymph node dissection. Our aim was to evaluate the role of three-dimensional transvaginal ultrasound (3D-TVUS) and diffusion-weighted magnetic resonance imaging (DW-RMI) for the assessment of myometrial infiltration in patients with well-differentiated (G1) or moderately differentiated (G2) endometrioid endometrial carcinoma (EC).

Methodology

We performed a retrospective observational study. Myometrial infiltration was assessed by 3D-TVUS and DW-RMI in 152 women with G1 or G2 endometrioid EC who underwent surgical treatment in a tertiary referral center between 2012 and 2019. Sensitivity, specificity, predictive values and accuracy for the two techniques and for a combination of both were computed. Definitive histopathological data in the surgical specimen regarding myometrial infiltration was used as ‘Gold Standard’.

Result(s)

One hundred and fifty-two patients were included, 120 (79%) patients presented myometrial infiltration <50% in postoperative analysis of surgical specimen and 32 (21%) patients presented deep myometrial infiltration (>50%). 3D-TVUS and DW-MRI showed an agreement of 78.9% with a kappa index of 0.44 for the detection of deep myometrial infiltration. Sensitivity, specificity and accuracy of 3D-TVUS for the detection of deep myometrial infiltration were 71.0%, 80.5% and 78.5% respectively. Evaluation of myometrial