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Detection of the HE4 protein in urine as a biomarker for ovarian neoplasms

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We have measured HE4 levels in urines and sera from normal donors, patients with ovarian neoplasms of low malignant potential (LMP) and ovarian cancer patients and correlated levels with clinical factors in ovarian cancer patients. Archived samples from controls, patients with LMP tumors and ovarian cancer were tested using commercial assays, as were serially collected serum and urine samples from women treated for stage III/IV serous ovarian cancer. Stage I/II and Stage III/IV serous ovarian cancer patients had HE4-positive urines similar to serum samples when tested at the same level of specificity (95%), while urine HE4 was more sensitive from patients with LMP tumors where 28% were HE4-positive versus 4% of sera (P=0.002). Mean levels of serum CA125 and HE4 decreased comparably in patients during initial treatment regardless of their primary platinum response, but mean urine HE4 levels decreased only 7% in primary platinum resistant patients while decreasing 68% in those who were sensitive. By 7 months after diagnosis, urine HE4 levels were higher in primary platinum resistant patients compared to those who proved to be sensitive (p=0.051) and persisted 12 months after diagnosis (p=0.014). HE4 values in urine also became positive in advance of clinical recurrence in several women while serum HE4 and serum CA-125 remained normal. We conclude that measuring HE4 in urine complements serum assays for the detection of ovarian cancer and propose that a "blinded" prospective study is performed on a much larger patient material and including women at increased risk for ovarian carcinoma.

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Early ovarian carcinoma: Clinical-pathological correlations and molecular studies

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Ovarian carcinoma (OC) is the most lethal gynecological tumor, most cases being diagnosed in late stages due to paucity of symptoms and absence of specific tumor markers in early stages of the disease. Preinvasive (dysplastic) lesions have been described in the ovaries by histologic, morphometric and immunohistologic methods, and in the fallopian tubes. Five year survival of OC is 30-35% in all stages and 80-90% in the rarely diagnosed stage I when the tumor is confined to the ovary(ies). Review of 99 cases of Stage I OC revealed a shift in the histologic distribution of early OC which are mostly non-Serous OC (NSOC) vs. the predominance of Serous OC (SOC) in all stages. The predominant early OC are endometrioid, mucinous and clear cell carcinomas. The rare Stage I SOC are detected randomly, most due to intense follow-up of high-risk patients (BRCA1/2 positivity, personal or family breast cancer). The clinical background of the patients is different in the NSOC patients who are younger, often hyperestrogenic and infertile, with coexisting endometriosis, endometrial polyps/hyperplasia/neoplasia, symptomatic lesions leading to an earlier diagnosis than the mostly asymptomatic SOC. Stage I OC is a heterogeneous group of tumors requiring different therapeutic approaches. Our recent molecular studies including markers, some of which targeting stem cells (HLA, Notch 3, Betacatenin, GLI-2, Cyclin E) offer an insight into early carcinogenesis of OC and may have an impact on therapeutic choices of this elusive and often deadly neoplasm.

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