OVA1 ovarian tumor triage test

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' objectives
Ovarian cancer is the fifth most common cause of cancer death other than skin cancer in women in the United States. Overall, a woman's lifetime risk of getting ovarian cancer is 1 in 73, but risk increases significantly post menopause, with the peak in the late 70s. Risk of dying from the disease is 1 in 101. A number of risk factors have been associated with the development of ovarian cancer, including a family history of ovarian cancer, nulliparity (i.e., the woman has never given birth), low parity (i.e., the woman has 1 or 2 children only), and the use of hormone replacement therapy. Women with a strong family history of inherited disease have a greatly increased risk of developing ovarian cancer, often at an earlier age than women in the general population. Approximately 3% to 13% of cases of ovarian cancer are due to heritable factors. This means, however, that 90% of women with ovarian cancer have no family history of the disease. Most ovarian cancers are epithelial in origin, and their prognosis is related to the stage of the tumor at the time of diagnosis. If the cancer is detected while it is still localized to the ovary, the 5-year survival rate can be 90% to 95%. However, since ovarian cancer causes few or no symptoms, most women with this disease present at an advanced stage, when the 5-year survival rate is 20% to 35%. Numerous guidelines have been published recommending that women with ovarian cancer be under the care of a gynecologic oncologist (GO); however, reports indicate that only one-third of women with malignant ovarian tumors are referred to a GO for surgery. Three primary methods have historically been assessed as possible ovarian screening tools for ovarian cancer: bimanual physical examination of the pelvis, pelvic ultrasound (US), and measurement of blood levels of the tumor marker CA-125. Used alone as a screening tool, pelvic examination lacks the sensitivity to identify early ovarian cancer. It is unclear whether any US techniques have a high enough sensitivity and specificity for screening the general population. Measurement of serum levels of the tumor marker CA-125 has a sensitivity of approximately 50% in early-stage cancers, and low specificity in premenopausal and postmenopausal women, and is not intended for preoperative assessment. The OVA1 test is an in vitro diagnostic multivariate index assay (MIA) of protein biomarkers intended to further assess the likelihood of malignancy in women presenting with an ovarian adnexal mass prior to planned surgery.

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