Diagnostics for early detection of ovarian cancer (Tel Hashomer)
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Diagnostics for early detection of ovarian cancer

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Abstract

According to the American Cancer Society, ovarian cancer is the 8th most common cancer among women in the United States. Ovarian Cancer is the 5th most common cause of cancer deaths in women and highest rate of deaths among the gynecologic cancers. Each year, more than 22,000 women in the U.S. are diagnosed with ovarian cancer and around 14,000 will die, the overall 5-year survival rate is only 46% in most developed countries. Late-stage diagnosis of high-grade ovarian carcinoma (HGOC) leads to high mortality rates.

There are 2 tests used most often to screen for ovarian cancer, the *transvaginal ultrasound*

Novel approaches are developed for ovarian cancer diagnosis such as whole genome techniques to directly profile DNA methylation aberrations in cancer, identification of tumor-specific exosomes in the blood of women with ovarian cancer, intra-fallopian tube sampling, uterine washing sampling and the sampling of cervicovaginal swabs.

HGOC arise from the fallopian tube epithelium (FTE), a liquid biopsy' may be obtained through washing of the uterine and tubal cavity, a procedure termed uterine lavage (UtL). We developed a method for deep proteomic profiling of microvesicles from UtL samples, which led to definition of a diagnostic signature for detection of HGOC and disease management.

The Need

Ovarian cancer is characterized by few early symptoms, presentation at an advanced stage, and poor survival. As a result, it is the most frequent cause of death from gynecological cancer.

Only 20% of ovarian cancers are found at an early stagewith 94% of survival rate longer than 5 years after diagnosis. Early detection and treatment should decrease mortality from this disease.

There is growing evidence that screening can impact on cancer specific mortality. Many countries have national screening programmers for breast, bowel, prostate, lung and cervical cancers with the latter associated with significant (50-90%) reduction in disease specific mortality. There is preliminary evidence that screening for ovarian cancer can improve survival, but there are currently no established international guidelines for ovarian cancer screening.

In addition, the population of women with inherited high-risk presents with a unique challenge: while the life-time risk of developing ovarian cancer is high, no screening program proved effective, and therefore women are advised to undergo a preventive surgery at age 40, even though the risk at this age is minimal and the consequences of loss of fertility and early menopause are significant. We believe that our research results may lead towards developing an early detection test for this particularly important population.

The Technology

We have identified protein biomarkers in body fluid sample obtained from the gynecologic tract by a minimally-invasive UtL procedure. The procedure can be easily performed in the clinic with minimal inconvenience and complications.

The first patient cohort, consisting of both ovarian cancer patients and women with other benign gynecological conditions, included 54 cases. It was used to build the 21-protein diagnostic signature which was then blindly applied to an independent validation set of 106 samples, and was capable of predicting the presence of HGOC with 55% sensitivity and 84% specificity. We currently continue enrolling patients, control women and women with high risk for HGOC in order to further improve the performance of the diagnostic signature.

The Product

A diagnostic kit for early detection of ovarian cancer.

This assay should be performed every 6 months from age 35 until the time of RRBSO. The kit will include software for targeted MS analysis of the specific signature proteins, and isotope-labelled standards for absolute quantification.

Alternatively, the product may be a kit for immunoassay for measurement of the signature proteins in liquid biopsies.

Applications

Early Diagnosis of Ovary Cancer.

A similar approach can be modified and applied for the development of diagnostic proteomic signatures for detection of other cancer types for which liquid biopsies are attainable.

Advantages

Only about 20% of ovarian cancers are found at an early stage. When ovarian cancer is found early at a localized stage, about 94% of patients live longer than 5 years after diagnosis, and better ways to screen for ovarian cancer are being researched.

The field of early-detection of ovarian cancer is unsaturated due to the recent failure of three large-scale screening trials.

The procedure is simple , can be done in the doctor clinic, and can be adapted to the market need of high risk population very fast.

The Market

Proteomics is expected to account for the largest share of the overall omics technologies market, followed by genomics and other omics technologies.

The overall cancer biomarkers market is estimated to grow ~$20.5B by 2022 from ~$11.5B in 2017, at a compound annual growth rate (CAGR) of 12.20 percent between 2017 and 2022.

The global ovarian cancer diagnostics market projects that by the end of 2017, around US$ 638 Mn worth of revenues will be procured globally through diagnosis of ovarian cancer. Towards the end of 2022, the global market for ovarian cancer diagnostics is anticipated to expand at 8.7% CAGR, bringing in revenues worth a little over US$ 966 Mn.

Some of the players in the ovarian cancer diagnostics market are AstraZeneca Plc.

Illumina, Inc., Bio-Rad Laboratories, Inc , Siemens AG , Roche Holding AG , Myriad Genetics, Inc. , Epigenomics AG, Thermo Fischer Scientific Inc., VolitionRx Ltd. , and Abcodia Ltd. to name a few.

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