Case Study

Presented by:
Luis Sanchez, MD
Loayza Hospital, Lima, Peru

iCellate cancer cell detection

Use of circulating tumor cell (CTC) screening for early detection of cervical cancer

Case description
The patient had no symptoms of cancer, however, during a routine check-up, the 61-year-old female patient was identified as belonging to a risk group due to her age and having a family history of cancer.
The patient was offered, and agreed, to be part of a screening study for disseminating cancer.
A standard peripheral blood draw was taken. The patient's subsequent circulating tumor cell test was positive, suggesting the possibility of a subclinical cancer.
She was referred to the gynecology clinic for further investigation, where a Papanicolaou (PAP) test confirmed a diagnosis of cervical cancer, validating the original suggestion.

Technique
A standard 10 ml peripheral blood draw was processed by iCellate´s novel technique to universally capture circulating tumor cells (CTC) from the large excess of normal blood cells. The technique captures CTCs independent of information on their cell surface molecules. iCellate´s test therefore allows capture of tumor cells even with initially unknown properties, providing unique access to the potentially most malignant, and therefore most diagnostically relevant cells, as they circulate. Once captured, the cells can be subjected to analyses of their detailed properties. That information allows the physician to make a more realistic, individualized, determination of the patient's needs for further investigation, including pinpointing the possible origin of the tumor cells, any need for treatment and if so, to suggest the best treatment option. In this case the circulating tumor cells (CTC) were simply identified and counted using established criteria.

Results
3 circulating tumor cells were discovered in a 10 ml peripheral blood sample. Acting on that information and referring to her family history, she was referred for further clinical investigation. The clinical investigation established a preliminary diagnosis of cervical cancer based on a Pap test.

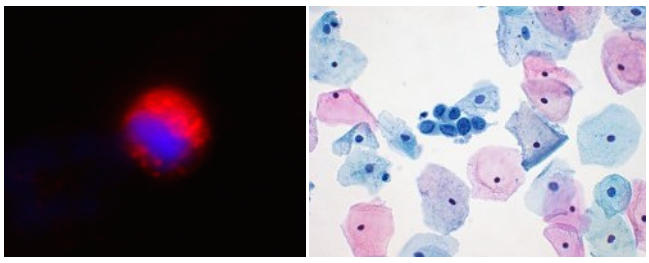

Figure 2. Circulating tumor cell (DAPI and cytokeratin positive, CD45 negative)

Figure 3. Pap test for atypical cervical cells (center, large blue nuclei)

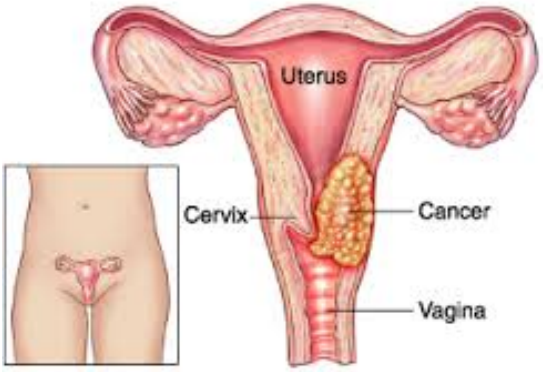

Figure 1. Cervical cancer (yellow)

Discussion
Recent data suggests that tumor cells spread from the primary tumor very early in the disease progression; perhaps even as early as when the first tumor cells first acquire malignancy.

The tumor cells can spread by way of the circulation to distant organs and form metastases. At this point the disease may also become resistant to treatment. Since metastasis is in fact known to be a very in-efficient process, there exists a possible window of opportunity to find the circulating tumor cells while in circulation but before they have had a chance to establish metastases.

Capturing CTCs has been a challenge, since they are very rare and are notorious for changing their properties. A method to capture CTCs universally and at high yield, based only on being different from the normal blood cells and not marker dependent solves the problem.

The clinically important properties could then be tested for, by established analytical techniques, such as antibodies or nucleic acid sequencing, on the captured cells.

Summary
iCellate Medical has established a technique to universally capture circulating tumor cells based on cells' biomechanical characteristics and therefore not marker dependent. It is now undergoing initial clinical testing. The present case study provides initial evidence that the laboratory results can be applied clinically to capture rare and changing tumor cells for further clinical testing. It has potential to revolutionize personalized cancer patient management and provide accurate early detection of cancer.

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