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PRESS RELEASE

Major advances in diagnosing cancers associated with the human papillomavirus

The Institut de Cancérologie de Lorraine [the Lorraine Institute of Oncology, or ICL] in collaboration with the Institut du Cancer Joliot Curie [the Joliot Curie Cancer Institute] in Dakar and the Cerba HealthCare Group has recently finalized research demonstrating that it is possible to diagnose certain cancers caused by the human papillomavirus (HPV) through a simple blood test.

Based on the innovative CaptHPV technique, this research recently published in the journal *Clinical Cancer Research** raises the prospect of a non-invasive approach to diagnosing certain cancers and optimizing biological monitoring of patients receiving therapy.

A ten-year scientific endeavour combining the expertise of public and private players

Studies conducted in the last twenty years have shown that small fragments of DNA from tumour cells are present in the blood of people with cancer. However, these fragments are difficult to locate since they are mixed in with large amounts of "normal" DNA.

Faced with the difficulty of distinguishing between tumour DNA and non-tumour DNA, ICL teams concentrated their efforts on types of cancers caused by viruses, specifically human papillomaviruses (HPV). They decided to test the hypothesis that it was possible to diagnose cancers associated with these viruses, regardless of the type of cancer or type of virus, in a different way. The ICL teams drew upon an innovative technique called CaptHPV, initially created to analyse tumours. For this new study, the technique was adapted to be used in analysing blood samples. This method makes it possible to detect all types of HPV identified to date and to obtain their full characteristics using what is called next-generation sequencing or NGS.

In 2016, the CaptHPV clinical trial was set up by the ICL in collaboration with a medical team from Senegal (a country with a different prevalence of certain types of HPV than France) and Cerba HealthCare, an expert in tumour biomarker analysis.

Promising results for diagnosing and monitoring patients

At the end of the study, the results obtained in each laboratory were compared. That comparison showed strong consistency between the two types of samples. More specifically, for 77 out of 80 patients with an HPV-associated cancer, the blood sample analysis yielded the same results as the tumour analysis, which is a sensitivity of 95%.

In just one of 54 cases of HPV-negative cancer, the blood test found fragments of viral DNA (a specificity of 98.1%). Furthermore, based on the blood sample, the original method provided a detailed description of the nature and characteristics of the viral genome associated with the tumour.

In certain situations, diagnosing HPV-associated cancer can be difficult using traditional approaches that rely on collecting a tumour tissue sample. This is particularly true for cases of suspected recurrence in a patient originally treated for a given type of tumour who now presents with minimal symptoms and deep

lesions that are difficult to distinguish on X-Rays or difficult to access. In these cases, but for all patients broadly speaking, blood sample analysis is a simple, non-invasive alternative to imaging-guided biopsies which can never be entirely risk free.

"Detecting viral DNA circulating in the blood would be an important biological component for optimising biological monitoring of patients during treatment as well as post-therapeutic observation. The fact that the viral profile of the tumour has previously been precisely defined will make it possible to know the main parameters on which the follow-up lab work will be based," explains Prof. Alexandre Harlé — a university lecturer and hospital practitioner at the ICL/University of Lorraine and the clinical pathologist responsible for the study coordination.

"In the longer term, it is very likely that new treatments -such as immunotherapy or therapeutic vaccine therapy- based on stimulating the immune system and aimed at viral sequences will require accurate prior knowledge of the characteristics of the viral sequences being targeted by these personalised treatments. Here again, being able to define the viral profile, regardless of the type of virus, based on a blood sample that can easily be repeated over time is a very interesting outlook," states Dr Xavier Sastre-Garau, a pathologist and principal investigator of the study.

Jérôme Sallette, Chief Scientific Officer of Cerba HealthCare, adds: "Liquid biopsies, and non-invasive diagnostic methods more generally, are a major area of research for cancer diagnosis thanks to the power of the next-generation sequencing that the Cerba HealthCare Group has successfully and routinely conducted since 2013. The opportunity offered by our skills in this area and the presence of our Group in Africa have been major advantages for our contribution to the work being done by the ICL. This work once again demonstrates the immense added value of public-private collaborations to advance research and to be able to offer patients and clinicians less invasive tools for earlier diagnoses. They lead to interesting possibilities for combat certain cancers in addition to screening, the importance of which cannot be stressed enough."

On a more fundamental level, this new approach will undoubtedly **improve our knowledge of the** biological mechanisms that influence tumour development.

In the long term, the work being conducted specifically on tumours associated with human papillomavirus should pave the way to optimizing diagnosis and monitoring of tumours associated with other viruses. Finally, the sensitivity and specificity observed in this study lay the groundwork for designing similar approaches for other types of tumours characterised by specific genetic alterations.

*Open access article (in English):

https://clincancerres.aacrjournals.org/content/early/2021/06/08/1078-0432.CCR-21-0293.long

About the Institut de Cancérologie de Lorraine (ICL - Lorraine Institute of Cancerology)

As a private health institution of public interest, member of Unicancer, the ICL dedicates its medical and paramedical activity to the diagnosis and treatment of cancers. Declared of public utility, it does not have any private sector activity or charge excess fees.

The institute treats nearly 16,000 patients a year.

As a Certified Clinical Research Center, the institute plays a significant role in research and takes part in many projects.

Deeply involved in oncology teaching activities, the ICL provides over 3,000 hours of teaching (training) per year in Lorraine, with a part certified "Continuing Professional Development".

It raises funds via donations and legacies in order to finance research, innovation or patient care projects. For more information: http://www.icl-lorraine.fr/

About Cerba HealthCare

Cerba HealthCare, a leading player in medical diagnosis, aims to support the evolution of health systems towards more prevention. It draws on more than 50 years of expertise in clinical pathology to better assess the risk of diseases development, detect and diagnose diseases earlier, and optimize the effectiveness of personalized medicine.

Every day, on 5 continents, the Group's 12,000 employees sustain the transformation of medicine, driven by one deep conviction: to advance diagnosis is to advance health.

Cerba HealthCare, *enlightening health*.

Additional information is available at www.cerbahealthcare.com

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