**Lisen Imprinting’s New Technology Eases Fear for HPV-Positive Patients**

**Breakthrough Published in Cancer Communications (IF=20.1): A Novel Early Cervical Cancer Detection Technology Developed by Lisen Imprinting and Sichuan University West China Second University Hospital**

**Wuxi, China –**

Lisen Imprinting Diagnostics (Wuxi) Co., Ltd. (“Lisen Imprinting”), in collaboration with Sichuan University West China Second University Hospital, has introduced a revolutionary non-invasive early detection technology for cervical cancer. This technology enables accurate risk assessment for HPV-positive individuals and holds significant implications for global cervical cancer prevention and control efforts.

On October 11, 2024, the internationally renowned oncology journal **Cancer Communications (IF=20.1)** published a research article titled ***"Genomic Imprinting Biomarkers for Cervical Cancer Risk Stratification."*** The study highlights Lisen Imprinting’s proprietary **Quantitative Chromogenic Imprinted Gene In Situ Hybridization (QCIGISH)** technology, which allows for a direct visualization of aberrant cancer-related imprinting gene expression within the cell nucleus. This approach quantifies cancer risk from an **epigenetic perspective**, offering a novel method for early detection.

**The Global Challenge of Cervical Cancer and the Need for Precise Risk Stratification**

Cervical cancer remains a major public health concern worldwide, with high incidence and mortality rates. In 2020, the World Health Organization (WHO) launched a global strategy to accelerate cervical cancer elimination through HPV vaccination, high-precision screening, and timely treatment. In China, a nationwide cervical cancer screening program was initiated in 2009 for women aged 35-64 and became part of the national basic public health services in 2019.

Since cervical cancer is primarily caused by HPV infection, HPV-DNA testing has become the standard for initial cervical cancer screening. However, as most HPV infections clear naturally without progressing to cancer, many HPV-positive individuals undergo unnecessary tests, leading to high medical costs, overburdened healthcare resources, and unnecessary anxiety. Therefore, a precise cervical cancer risk stratification method is needed to distinguish low-risk cervical lesions from high-risk precancerous and early-stage cervical cancer cases, ensuring timely diagnosis and treatment.

**Imprinting Genes: A Novel Biomarker for Early Cancer Detection**

Imprinting genes play a crucial role in cell proliferation and differentiation during embryonic development. Normally, one allele is active while the other is silenced due to epigenetic modifications inherited from parents. However, in cancer, these epigenetic modifications become dysregulated, leading to aberrant gene expression, excessive cell proliferation, and tumor formation. Since these imprinting gene expression changes occur at the earliest stages of cancer development, they serve as sensitive biomarkers for early cancer detection.

**Clinical Study Confirms QCIGISH’s High Accuracy in Cervical Cancer Screening**

In collaboration with Sichuan University West China Second University Hospital (West China Women’s and Children’s Hospital), Chengdu Women and Children's Central Hospital, Zigong Maternal and Child Health Hospital, Chenghua District Maternal and Child Health Hospital in Chengdu, and Nanjing First Hospital, Lisen Imprinting conducted a study analyzing 259 clinical samples to validate imprinting gene biomarkers for cervical cancer risk stratification.

The prospective validation demonstrated that in non-invasive cervical smear samples, QCIGISH technology achieved:

* 93.8% sensitivity and 83.6% specificity for detecting precancerous lesions and cervical cancer.
* When HPV-positive individuals tested negative with QCIGISH, 96.8% were confirmed as low-risk and did not require additional tests.
* Even among high-risk HPV-16 and HPV-18 infections, the proportion of low-risk lesions in QCIGISH-negative individuals reached 92%.

By stratifying risk with QCIGISH, **unnecessary colposcopies could be avoided in 89.1% of benign lesions and 68.4% of low-risk lesions**, significantly improving screening efficiency and alleviating anxiety among HPV-positive patients.

**Expert Opinions on the Study’s Impact**

**Prof. Liu Hanmin, President of Sichuan University West China Second University Hospital (Corresponding Author):**

*"Imprinting gene-based cervical cancer risk stratification offers a critical tool for addressing this global public health issue. Lisen Imprinting’s QCIGISH technology will optimize screening workflows, reduce medical costs, and enhance early diagnosis and treatment of cervical cancer. This groundbreaking clinical study, led by our team, contributes significantly to public health and, combined with widespread HPV vaccination efforts, brings China closer to becoming one of the first countries to achieve WHO’s cervical cancer elimination goal."*

**Prof. Xiao Xue, Vice President of Sichuan University West China Second University Hospital (Co-First Author):**

*"Clinically, we often face two opposing challenges: Many HPV-positive patients undergo unnecessary tests, while many precancerous and early cervical cancer cases go undetected. The imprinting gene-based risk stratification technology precisely excludes low-risk lesions, reducing anxiety among HPV-infected individuals, while sensitively detecting precancerous lesions and carcinoma in situ to enable timely treatment. Our multicenter study advances precision medicine for cervical cancer and may have a profound impact on global early screening and management protocols."*

**Prof. Chen Ying, Chengdu Women and Children's Central Hospital (Co-First Author):**

*"Non-invasive early detection of cervical cancer has long been a challenge, as subtle cellular changes are difficult to identify, leading to missed diagnoses even with active follow-ups. However, premature colposcopic biopsies may cause unnecessary trauma. The QCIGISH technology addresses this challenge by transforming* ***invisible molecular changes*** *into* ***visible biomarker signals****, making* ***non-invasive early cervical cancer diagnosis feasible****. Thanks to our collective efforts, this breakthrough will greatly enhance early cervical cancer diagnosis and treatment."*

**Lisen Imprinting’s Future Vision for Early Cancer Detection**

**Dr. Zhou Ning, Founder and CEO of Lisen Imprinting (Corresponding Author):**

*"I am delighted to see our cervical cancer detection technology successfully validated in clinical studies. Following our previous advancements in thyroid nodule and lung nodule diagnostics, this marks our third major achievement in translating cutting-edge research into clinical applications. Moving forward, we will continue fostering industry-clinical collaborations to bring the latest biotechnologies into clinical practice, benefiting cancer patients in China and globally."*

Dr. Zhou further emphasized that Lisen Imprinting is committed to advancing imprinting gene detection technology for early cancer diagnosis. Headquartered in Wuxi, China, with a clinical translation and validation lab in Wilmington, Delaware, USA, the company is developing a range of QCIGISH-based early cancer detection solutions, including thyroid cancer, lung cancer, cervical cancer, breast cancer, bladder cancer, and prostate cancer.

To date, Lisen Imprinting’s QCIGISH technology has been clinically validated in over 10 cancer types, involving thousands of patients. Previous findings have been published in leading academic journals such as Clinical Epigenetics and the Journal of Clinical Oncology, covering QCIGISH methodology, imprinting gene-based lung cancer detection, and thyroid nodule diagnostics. As a valuable complement to biopsy cytology, imprinting gene tumor detection technology significantly improves preoperative diagnostic accuracy, providing critical guidance for clinical treatment decisions.

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