Official title: Clinical Study on Predicting Lymph Node Metastasis of High-risk Prostate Cancer Based on Artificial Intelligence Multi-omics Analysis：A Multicenter, Prospective and Observational Clinical Study

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Research institution: The First Affiliated Hospital of Anhui Medical University

Principal Investigator (Responsible Research Physician): Sheng Tai

You are being invited to participate in a clinical research study. This notice is provided to help you decide whether to participate in this clinical study. Please read it carefully and ask the researcher in charge of this study if you have any questions.

Your participation in this study is voluntary. This study has been reviewed by the Institutional Ethics Review Committee.

Research objectives: Based on artificial intelligence technology, by outlining the quantitative mapping correlation between annotated images of prostate cancer tissue whole sections, magnetic resonance imaging, and the presence of pelvic lymph node metastasis, common characteristics were identified and a lymph node metastasis prediction model for high-risk prostate cancer patients was established. First, the model can accurately predict whether pelvic lymph node metastasis is present before surgery, eliminating unnecessary pelvic lymph node dissection and avoiding postoperative complications associated with pelvic lymph node dissection, such as lymphatic leakage and lymphatic fluid infection. Second, the established artificial intelligence prediction model can accurately diagnose the lymph node metastasis, invasion, grade, sub-type and probability of biochemical recurrence of prostate cancer by predicting the subject's magnetic resonance imaging and biopsy pathological tissue images before surgery or puncture.

Research process: This study plans to enroll 2,000 subjects, with each patient receiving one MRI image and two prostate tissue pathology slide. A total of 2,000 MRI images and 4,000 pathology slides are expected to be collected. Each MRI image will contain a complete image sequence, including T1-weighted, T2-weighted, DWI, and ADC images. Each pathology slide will contain a complete tissue section and undergo hematoxylin-eosin staining and immunohistochemistry. MRI images will be used to develop an artificial intelligence model to predict lymph node metastasis, invasion,

grade, and sub-type of prostate cancer. Prostate tissue pathology slides will be mapped with MRI images to verify the accuracy of the artificial intelligence model and assist in clinical immunohistochemical diagnosis.

Risks and Discomfort: All your information will be kept confidential. Your sample will be collected in strict accordance with aseptic requirements. There may be some very small risks during specimen collection, including brief pain, local bruising, mild dizziness in a few people, or extremely rare needle infection.

Benefits: You will not receive immediate benefits from participating in this study, but the established multi-omics lymph node metastasis prediction model for prostate cancer patients can accurately analyze whether a patient has lymph node metastasis and develop a more personalized treatment plan for the patient. This will help further improve the treatment efficacy of prostate cancer, may provide necessary advice for your treatment, or provide useful information for disease research.

Cost: Patients do not bear the cost of clinical trials. All expenses incurred during the diagnosis and treatment process must be borne by the patient.

Compensation: No compensation

As a research subject, you have the following responsibilities: provide a true account of your medical history and current physical condition; tell the research doctor any discomfort you experience during the study; do not take restricted medications, foods, etc; tell the study doctor if you have recently participated in or are currently participating in other research studies.

Privacy Issues: if you decide to participate in this study, your research and individuals involved in research information will be kept confidential. Your biological specimens will be identified by a study number, not your name. Personally identifiable information will not be disclosed to anyone outside the research team without your permission. All research team members and the study sponsor are required to maintain confidentiality regarding your identity. Your file will be kept in a locked cabinet and accessible only to researchers. To ensure the research is conducted in accordance with regulations, your personal data may be accessed by government regulatory authorities or members of the ethics review committee at the research site, as required. No personal information will be disclosed when the results of this study are published.

If you are harmed by participating in this study: You may receive free treatment and/or compensation for any damages related to this clinical study.

You may choose not to participate in this study, or notify the researcher at any time to request to withdraw from the study. Your data will not be included in the research results, and your medical treatment and rights will not be affected.

Disposal of biological samples and information after the study: Excess biological samples after testing will be kept by the First Affiliated Hospital of Anhui Medical University. These samples may not be sent outside of mainland China without the approval of the First Affiliated Hospital of Anhui Medical University. The ownership and use rights of the laboratory data of the submitted biological samples belong to the First Affiliated Hospital of Anhui Medical University.

The study physician may terminate your participation in this study if you require additional treatment, if you do not comply with the study plan, if you develop a study-related injury, or for any other reason.

You can keep informed of the information and research progress related to this study at any time. If there is any new safety information related to this study, we will also notify you in a timely manner. If you have any questions related to this study, or if you experience any discomfort or injury during the study, or if you have any questions about the rights of participants in this study, you can contact us through+86-+18355159268 (*phone number*)and Sheng Tai.

If you have any questions or concerns about your rights and health as a participant in this study, please contact the Ethics Committee of this institution at +86-551-62923102; Contact: Yihao Chen

Informed consent signature page

I have read this Informed Consent Form.

I have the opportunity to ask questions and all of them were answered.

I voluntarily participate in this study.

I can choose not to participate in this study, or withdraw after notifying the researcher at any time without being discriminated against or retaliated against, and any of my medical treatment and rights will not be affected.

- The study physician may terminate my participation in this study if I require additional treatment, if I fail to comply with the study plan, if I develop a study-related injury, or for any other reason.

I will receive a signed copy of the Informed Consent Form.

Subject's name: _____

Subject's Signature: _____

Date: _____

I have accurately informed the subject of this document and asked him/her to read this informed consent carefully and answered any questions or doubts raised carefully.

Researcher's Name: _____

Investigator's Signature: _____

Date: _____

(*Note: If the subject is illiterate, a witness signature is required; if the subject is incapable of acting, an agent signature is required.*)