

Harbin Medical University
Institutional Research Board Report

No.: HMUIRB20160017

The research on **Combination of three-gene immunohistochemical panel and MRI-detected extramural vascular invasion to assess prognosis in non-advanced rectal cancer patients** is intended to be carried out by Dr. Xiao Fu Li of Harbin Medical University. The program is based on the human samples and MRI images as the objects of study. Ethical board approval from the Human Ethics Review Board, Harbin Medical University is on the process.

1. Program Information

1) **Research project title:** Combination of three-gene immunohistochemical panel and MRI-detected extramural vascular invasion to assess prognosis in non-advanced rectal cancer patients

2) **Undertaking project enterprises:** Department of Magnetic Resonance Imaging, The 2nd Affiliated Hospital, Harbin Medical University, Harbin, Heilongjiang, China

3) **Project leader:** Xiao Fu Li; **Position:** Attending physician

4) **Dates of the program:** From 7/2011 to 7/2014

2. Chief Content of study

ABSTRACT

Background: Non-advanced rectal cancer (RC) can be treated using various strategies. The accuracy of preoperative staging is vital in the modern management. In order to accurately classify prognostic risks, this study set out to identify a small, clinically applicable immunohistochemistry (IHC) panel which combined with MRI-detected extramural vascular invasion (EMVI) for preoperative prognostication in RC patients..

Methodology/Principal Findings: Patients who underwent rectal MRI between July 2011 and July 2014 were screened. This study included 329 patients with pathologically confirmed RC who had undergone MRI without previous treatment. The candidate proteins reported to be altered in RC tissues were examined by immunohistochemistry (IHC). Of the three proteins tested, c-MYC, PCNA and TIMP1 were detected with high expression in 35.9%, 23.7% and 58.7% of tumors, respectively. Significant associations were found between expression of these proteins and prognosis ($P=0.032$, 0.003 , 0.021). Applying these three proteins as an IHC panel could divide patients into different subgroups ($P < 0.01$). Adjusting for known survival covariates, including EMVI, the IHC panel remained an independent prognostic factor. Combination of EMVI and the IHC panel could separate patients into distinct prognostic groups ($P < 0.01$).

Conclusions/Significance: The data suggest that the three-protein panel of c-MYC, PCNA and TIMP1 combined with MRI-detected EMVI could provide additional prognostic information for preoperative treatment decision-making of RC.

3. Review evaluation opinions

Safety and fairness principle has been fully considered in the experiments plans. All of the volunteers gave written informed consent, and the content of the research have no harm or risk. Before the research was conducted, ethical board approval from the Harbin Medical University was obtained. No conflict of interest exists in this study.

4. Conclusion

The rights and interests of patients subjects have been adequately protected in the study, and there is no potential risk to the patients. Agree to the study work as planned.

Institutional Research Board of Harbin Medical University

07/05/2016

