

Chinese guideline for the application of rectal cancer staging recognition systems based on artificial intelligence platforms (2021 edition).

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Chin Med J (Engl) Chin Med J (Engl) 2337 chinesemj 7513795 CM9 Chinese Medical Journal 0366-6999 2542-5641 Wolters Kluwer Health PMC8183759 PMC8183759.1 8183759 8183759 34075899 10.1097/CM9.0000000000001483 CMJ-2021-002 1 Consensus Statements Chinese guideline for the application of rectal cancer staging recognition systems based on artificial intelligence platforms (2021 edition) Gao Yuan 1 Lu Yun 1 Li Shuai 2 Dai Yong 3 Feng Bo 4 5 Han Fang-Hai 6 Han Jia-Gang 7 He Jing-Jing 8 Li Xin-Xiang 9 10 Lin Guo-Le 11 Liu Qian 12 Wang Gui-Ying 13 Wang Quan 14 Wang Zhen-Ning 15 Wang Zheng 16 Wu Ai-Wen 17 Wu Bin 18 Yang Ying-Chi 19 20 Yao Hong-Wei 19 20 Zhang Wei 21 Zhou Jian-Ping 22 Hao Ai-Min 2 23 Zhang Zhong-Tao 19 20 Colorectal Surgery Group of the Surgery Branch in the Chinese Medical Association; Beihang University State Key Laboratory of Virtual Reality Technology and Systems Ji Yuan-Yuan 1 Department of General Surgery, The Affiliated Hospital of Qingdao University, Qingdao, Shandong 266555, China 2 Beihang University State Key Laboratory of Virtual Reality Technology and Systems, Beijing 100191, China 3 Department of General Surgery, Qilu Hospital of Shandong University, Jinan, Shandong 250012, China 4 Department of General Surgery, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai 200025, China 5 Shanghai Minimally Invasive Surgery Center, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai 200025, China 6 Department of Gastrointestinal Surgery, Sun Yat-sen University, Guangzhou, Guangdong 510120, China 7 Department of General Surgery, Beijing Chaoyang Hospital, Capital Medical University, Beijing 100020, China 8 Institute of International Law, Chinese Academy of Social Sciences, Beijing 100732, China 9 Department of Colorectal Surgery, Fudan University Shanghai Cancer Center, Shanghai 201321, China 10 Department of Oncology, Shanghai Medical College, Fudan University, Shanghai 201321, China 11 Department of General Surgery, Peking Union Medical College Hospital, Peking Union Medical College, Chinese Academy of Medical Sciences, Beijing 100730, China 12 National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences, Peking Union Medical College, Beijing 100021, China 13 Third Hospital of Hebei Medical University, Shijiazhuang, Hebei 050051, China 14 Department of Colon and Rectum Surgery, The First Hospital of Jilin University, Changchun, Jilin 130021, China 15 Department of Surgical Oncology and General Surgery, Key Laboratory of Precision Diagnosis and Treatment of Gastrointestinal Tumors, Ministry of Education, The First Affiliated Hospital of China Medical University, Shenyang, Liaoning 110001, China 16 Department of Gastrointestinal Surgery, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei 430022, China 17 Department of Unit III & Ostomy Service, Key laboratory of Carcinogenesis and Translational Research (Ministry of Education), Gastrointestinal Cancer Center, Peking University Cancer Hospital & Institute, Beijing 100142, China 18 Department of General Surgery, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, Peking Union Medical College,

Beijing 100730, China 19 Department of General Surgery, Beijing Friendship Hospital, Capital Medical University, Beijing 100050, China 20 Beijing Key Laboratory of Cancer Invasion and Metastasis Research, National Clinical Research Center of Digestive Diseases, Beijing 100050, China 21 Colorectal Surgery Department, Changhai Hospital, Naval Medical University, Shanghai 200433, China 22 Department of Gastrointestinal Surgery & Hernia and Abdominal Wall Surgery, The First Hospital, China Medical University, Shenyang, Liaoning 110001, China 23 Beijing Advanced Innovation Center for Biomedical Engineering, Beijing 100191, China. Correspondence to: Dr. Zhong-Tao Zhang, Department of General Surgery, Beijing Friendship Hospital, Capital Medical University; Branch Center of General Surgery, National Clinical Research Center for Digestive Diseases; Capital Medical University, Clinical Center for Colorectal Cancer, Beijing 100050, China E-Mail: zhangzht@ccmu.edu.cn ; Dr. Ai-Min Hao, Beihang University State Key Laboratory of Virtual Reality Technology and Systems, Beijing Advanced Innovation Center for Biomedical Engineering, Beijing 100191, China E-Mail: ham@buaa.edu.cn 05 6 2021 28 4 2021 134 11 383365 1261 1263 03 1 2021 05 06 2021 07 06 2021 05 04 2026 Copyright © 2021 The Chinese Medical Association, produced by Wolters Kluwer, Inc. under the CC-BY-NC-ND license. 2021 <https://creativecommons.org/licenses/by-nc-nd/4.0/> This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. <http://creativecommons.org/licenses/by-nc-nd/4.0/> pmc-status-qastatus 0 pmc-status-live yes pmc-status-embargo no pmc-status-released yes pmc-prop-open-access yes pmc-prop-olp no pmc-prop-manuscript no pmc-prop-legally-suppressed no pmc-prop-has-pdf yes pmc-prop-has-supplement yes pmc-prop-pdf-only no pmc-prop-suppress-copyright no pmc-prop-is-real-version no pmc-prop-is-scanned-article no pmc-prop-preprint no pmc-prop-in-epmc yes pmc-license-ref CC BY-NC-ND OPEN-ACCESS TRUE Development and Application of Artificial Intelligence Recognition Systems in Rectal Cancer Staging Whether for surgical treatment or for neoadjuvant chemoradiotherapy, imaging evaluation has become an important basis to perform the treatment plans. [1] The reading of imaging results requires a large number of experienced radiologists to complete, but shortages and uneven distributions of personnel cause delays and biases in imaging results. Therefore, independent research and development of automatic recognition systems of rectal cancer staging based on artificial intelligence (AI) platforms aim to partially replace practitioners' work and achieve rapid and accurate identification of rectal cancer staging.

Faster region-based convolutional neural networks (FR-CNNs) were utilized to learn and train from a large number of images and build a network for the identification and labeling of lesions, the automatic delineation of target areas, and three-dimensional reconstruction. According to the requirements of the National Comprehensive Cancer Network guidelines, pre-operative evaluation is mainly based on the tumor-node-metastasis (TNM) staging system and the circumferential resection margin (CRM). [2] The guideline decided to take "T, N, CRM, and extramural vascular invasion (EMVI)" as the pre-operative evaluation factors of rectal cancer staging, and the AI recognition system was used to complete the evaluation of tumor staging.

Magnetic resonance imaging (MRI) images were acquired using GE, Siemens, Philips, and other 3.0T MRI scanners configured in most hospitals. The main scanning sequence and parameters are listed for reference in Supplementary Table 1. After image collection was completed, the corresponding sequence images with diagnostic value for an input in the deep neural network (DNN) were selected to establish the database.

Based on the decision of the expert committee, provisions were made for the identification of four parameters in the training set. [3 , 4] T staging was defined in MRI based on the TNM staging system of the American Joint Committee on Cancer [5] and Horvat et al 's study [6] : (a) T1 tumors infiltrate the submucosa; (b) T2 tumors extend into the muscularis propria; (c) T3 tumors are characterized by a discontinuity of the muscularis propria, with the extension of the tumor into the mesorectum; and (d) T4 tumors are those that infiltrate the peritoneal reflection or other pelvic organs and structures. According to international consensus, the size, shape, and signal of lymph

nodes (LNs) are used as the diagnostic basis for metastasis [6 – 8] : (a) The smallest diameter on T2 weighted image (T2WI) of MRI was ≥ 5 mm; (b) Irregular in shape and indistinct in edge; (c) Dispersion enhanced imaging shows high signal; and (d) Upper and lower discontinuities between the image layers were considered LN positive. For positive judgments of CRM on MRI, we adopted the criteria of the MERCURY Research Group [9] : Positive CRM was considered when the distance between the outer edge of the tumor and the mesenteric fascia was ≤ 1 mm. For positive judgments of EMVI on MRI, we used the scoring system from the study of Smith et al [10] : On MRI T2WI, (a) The moderate signal intensity was evident in the blood vessels, but the contour and caliber of these vessels were only slightly enlarged and (b) The tumor signal is clear, the vascular shape is obviously irregular or nodular dilatation [Supplementary Figure 1A].

Two senior imaging experts and one colorectal surgery expert were selected to jointly evaluate and mark the correlation factors of rectal cancer staging on the images at the corresponding level of the MRI sequence. In case of any inconsistency between the diagnostic results of the three experts, a fourth imaging expert was consulted, and a final conclusion was reached. For each patient, approximately three marked images with diagnostic value were selected for input into the DNN to study the DNN platform and establish the corresponding MRI image database. [11 – 13]

We used FR-CNN to realize the automatic detection of rectal cancer staging parameters. The system was composed of two modules: a region proposal network and a module based on the candidate areas of the FR-CNN target detector [Supplementary Figure 2]. Two common parts were combined into a whole and unified target detection network, and by sharing the same convolution layer, the bounding box of the suspected lesions served as the image output with the parameters of the output probability scores [Supplementary Figure 1B]. [14 , 15]

We use receiver operating characteristic (ROC) and precision-recall (PR) curves as evaluation tools for clinical verification of the AI automatic recognition system for MRI image-assisted diagnosis. Both ROC and PR are excellent evaluation tools in the field of detection and classification involving DNNs. However, most of the area under the curve (AUC) indicators in the current studies were obtained based on ROC curves, so the AUC value of the final evaluation indicator in this study was also calculated based on the ROC curve [16] [Supplementary Figure 3].

AI recognition system through deep learning and verification needs to achieve higher accuracy evaluation indexes, and ROC curve evaluation is recommended. When $AUC \geq 90\%$ is obtained, the AI recognition system will enter the clinical application. The AI recognition system will locate and calculate probabilities for the four indicators of T staging, N staging, CRM, and EMVI of rectal cancer to provide a reference for clinicians in the judgment of pre-operative staging of rectal cancer and the formulation of diagnosis and treatment plan. When using the AI recognition system, clinicians will make accurate judgments based on the probability of each indicator. Therefore, this guideline divides the probability into three levels based on previous studies and clinical applications: Highly reliable, possible compliance, and poor compliance. The probability of high reliability includes: T staging $\geq 90\%$, N staging, CRM, or EMVI $\geq 80\%$; the possibility of possible compliance includes: $90\% > \text{T staging} \geq 70\%$, $80\% > \text{N staging}$, CRM or EMVI $\geq 60\%$; the probability of poor compliance includes: T staging $< 70\%$, N staging, CRM or EMVI $< 60\%$.

This guideline is recommended for high-resolution MRI images of patients with rectal cancer, and the results are input into the AI recognition system to obtain the identification results of T staging, N staging, CRM, and EMVI as four parameters. For T1N0, early colorectal cancer patients, transanal local resection, transanal endoscopic microsurgery, or transanal minimally invasive surgery can be chosen. For pre-operative evaluation results that do not meet the above conditions, including the possibility of lateral LN metastasis, pre-operative neoadjuvant chemoradiation is recommended, then secondary identification is performed using the AI recognition system. To achieve the clinical complete response (cCR), transanal local resection or watch and wait strategy is then recommended. For patients who have not reached the cCR, radical TME surgery is recommended. In addition, if the secondary identification still identifies lateral LNs metastasis in patients, selective lateral LNs dissection is recommended and performed [17] [Supplementary Figure 4].

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