

Development and Application of Digital Pathology in China

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Abstract

Nowadays, digital pathology has revolutionized the traditional mode of pathology work and has brought about significant advancements in the field. This technology provides a stronger foundation for accurate diagnosis and serves as an inevitable trend in the development of pathology. With the advancement of computer and network technology, digital pathology has undergone three stages of development. It has evolved from digital scanning equipment to a pathological cloud platform and now includes artificial intelligence-aided diagnosis. These advancements have consistently driven the new development of accurate diagnosis. Digital pathology is being increasingly used in clinics. Currently, the three primary applications in the field of pathology are pathology department management, remote pathological consultation, and pathological artificial intelligence. Among these, remote pathological consultation is the most well-established field, as it enables standardized management of pathology departments, significantly reduces the workload of pathologists, improves the accuracy and efficiency of clinical pathological diagnosis, and enhances the level of pathological diagnosis in primary hospitals. Digital pathology is a relatively new technology, but there are still some challenges that need to be addressed and continuously improved upon. This paper discusses the development stage, application, and challenges of digital pathology, and presents future development prospects and opportunities.

Keywords

Digital pathology, Management of pathology department, Remote consultation, Artificial intelligence

Pathological diagnosis is the "gold standard" in disease diagnosis. The number, professionalism and accuracy of examination of pathologists directly determine the development level of the diagnosis industry.

At present, pathologists are scarce in China. According to the data of China Health Statistical Yearbook, by the end of 2018, there were 18,000 registered pathologists (including licensed doctors and assistant licensed doctors) in China, while the number of pathologists allocated according to the number of clinical beds in 2018 was 84,000-168,000, so the gap of pathologists was more than 66,000. However, a pathologist who can independently issue pathological reports usually needs more than 10 years of training cycle, which leads to a large amount of diagnosis and heavy work for pathologists. Moreover, the distribution of pathologists' resources in China is unbalanced, pathologists in grass-roots hospitals are even more scarce and the medical level is generally low. Nowadays, the incidence of cancer in the world is rising year by year, and the gap in the number of pathologists is increasing, which leads to the increasingly heavy workload of pathologists and high technical requirements for pathologists, which makes pathologists bear great pressure to read films and easily affects the accuracy of diagnosis.

In recent years, with the rapid development of image digitization and network transmission technology, pathology has completed the transformation from traditional pathology to digitalization. It has entered the era of digital pathology. Digital pathology not only improves the accuracy and efficiency of pathological diagnosis, reduces the workload of pathologists, and saves costs, but also improves the level of pathological diagnosis in primary hospitals, which is the inevitable trend of the development of pathology departments [1].

Digital pathology (DP) refers to the technology of applying computer, network technology, and digital image technology to pathology collection, storage, and auxiliary diagnosis based on traditional pathology with a microscope as the main tool [2].

1. The development of digital pathology

European and American countries entered the era of digital pathology a little earlier than China, but digital pathology is a new global technology. Now, the development of digital pathology in European and American countries and China is almost at the same starting line. China's digital pathology has developed for more than 20 years. The exploration of digital pathology in China began in 1996. Beihang Image Center developed a point-to-point static remote pathological diagnosis system through telephone lines. Since then, many domestic units have tried to establish remote pathological websites to carry out difficult pathological diagnoses, academic exchanges, teaching and providing relevant pathological information. With the development of technology, digital pathology diagnosis in China began to be commercialized. The period from 2013 to 2019 was the rapid development period of digital pathology in China, and digital pathology in China achieved a leap-forward development.

The development of digital pathology in China has gone through the following stages [3]:

The first stage: with the continuous development of digital scanning technology, the traditional slice information is digitized, which can store and transmit information more conveniently and efficiently. With the application of Whole Slide Imaging (WSI) and other technologies, digital storage of slice information and digital archiving of pathological information is realized. With the help of WSI technology, remote consultation of pathology is realized through a computer network, which can not only realize domestic remote consultation and improve the diagnostic ability of primary hospitals in China but also participate in international remote consultation, so that Chinese pathologists can participate in remote consultation in developed countries and serve other developing countries, which makes pathological diagnosis break through the limitations of time and region and improve the diagnostic efficiency and level.

The second stage: Based on the further application of WSI technology and the development of cloud technology, a "digital pathology cloud" platform is constructed, which represents the pathology department entering the full digital pathology stage in Internet Plus. The "Digital Pathology Cloud" platform enables the traditional pathology department to develop into a fully digital pathology department in Internet Plus. A large number of cases on the platform can be shared and studied by pathologists, and pathologists can also provide remote diagnosis services on the cloud platform. Grassroots pathologists can also obtain diagnostic experience accumulation, remote training, and remote quality control through the cloud platform, to improve the diagnostic level.

The third stage: With the continuous development of deep learning and artificial intelligence, AI-aided diagnosis is realized. Through the software system, the process of film reading, labeling, registration, and analysis can be fully automated, which can replace repeated time-consuming, and laborious work and improve the accuracy and efficiency of pathological diagnosis. The application of artificial intelligence aided diagnosis to tumor diagnosis, such as breast cancer, colorectal cancer, cervical cancer, prostate cancer, and other tumor diagnosis applications, can provide pathologists with automatic diagnosis work and realize high-accuracy and high-speed pre-diagnosis process. The application of artificial intelligence based on deep learning in digital pathology has become one of the research hotspots [3, 4].

Nowadays, all-digital and intelligent pathology has become a hot spot in medical research, and AI pathology has become a sunrise track of great concern in the industry.

2. Application of Digital Pathology

2.1 Pathology Department Management

Nowadays, some pathology departments/laboratories around the world have completed all-digital conversion, and established standard digital pathology storage systems and workflow. The application results show that the scanning speed of slices is greatly improved and the diagnostic efficiency is greatly improved. For example, the

Department of Anatomy and Pathology of the University Hospital of Granada, Spain, implemented a fully digital pathological diagnosis process, and the results showed that the diagnostic efficiency was improved by 20% [5].

Many pathological departments in China have used advanced digital scanners to capture digital slices, store them, analyze them and share them with others. The tedious and time-consuming work is completed by computers, which saves time and reduces costs, making pathological diagnosis faster and more efficient.

At the same time, many pathology departments in China have not only realized digital transformation but also realized information transformation. By adopting the pathological information management system, the pathology department has realized the unified management of the whole process, such as pathological specimen registration, image acquisition, quality control management of production process, pathological report diagnosis, review and distribution management, information archiving and management, information resource sharing, etc., and achieved the goals of the whole process of quality control, workflow standardization and diagnosis process standardization in the pathology department, and realized the process optimization, reduced operating costs and improved service quality and work efficiency in the pathology department.

Many hospitals in China, such as Henan Provincial People's Hospital, Shanghai Zhongshan Hospital, and Zhongshan People's Hospital, have built fully digital pathology departments to promote the automation, standardization, and standardization of pathological detection with innovative technologies. For example, the Cancer Hospital affiliated with Fudan University has built a fully digital intelligent pathological in-hospital diagnosis system. It has continuously strengthened iterative upgrading, and further strengthened the standardized and modern management of clinical pathology laboratories. It promoted the high-quality development of clinical pathological detection and diagnosis, thus providing high-quality and accurate medical services for more patients.

2.2 Pathological remote consultation

At present, pathological remote consultation is the most widely used field of digital pathology, and it is also one of the important solutions to solve the problem of diagnosis of difficult cases and alleviate the contradiction of lack of resources for pathologists in primary hospitals.

Digital pathological remote consultation mainly transmits high-quality digital pathological pictures and related medical history to the diagnosis platform through a digital slice scanner, remote consultation platform, and computer network, so that pathologists, doctors, patients, and their families can consult in different places, freely read digital slice information, discuss illness and study. By configuring digital slice scanning and remote consultation systems in grass-roots medical institutions, remote consultation between grass-roots hospitals and superior hospitals can be realized, pathological equipment and high-quality medical resources of superior hospitals can be shared, the allocation of medical resources can be optimized, the shortage of pathological diagnosis in grass-roots hospitals can be alleviated, the ability of disease diagnosis and treatment in grass-roots hospitals can be improved, and the development of primary medical undertakings in China can be promoted [6]. For example, the Department of Pathology of the First Affiliated Hospital of Kunming Medical University conducted remote consultation on pathology by selecting its grass-roots branch, and compared with our hospital, it was found that remote consultation on pathology can not only help the grass-roots hospital make a quick diagnosis, improve the efficiency of diagnosis and treatment, but also help patients save the cost of diagnosis [7].

Nowadays, pathological remote consultation has been greatly promoted and popularized in China. With the research led by the Digital Pathology and Artificial Intelligence Pathology Group of China Pathologists Association, more than 1 million cases of remote pathological diagnosis have been completed in China from 2011 until March 2019, which has greatly promoted the level of pathological diagnosis and graded diagnosis and treatment in primary hospitals, benefiting more patients [8].

2.3 Pathological artificial intelligence

When artificial intelligence is applied to pathological diagnosis, it can transmit, store, label, and analyze digital images, automatically screen abnormal cells, automatically diagnose and report, etc., to realize AI quantitative diagnosis, AI visualization, and AI report, assist pathologists in pathological diagnosis, and greatly improve the diagnostic efficiency and diagnostic accuracy of pathologists browsing slices.

Artificial intelligence-assisted pathological diagnosis is mainly based on computer deep learning. At present, the deep learning models commonly used to analyze pathological images mainly include convolutional neural networks, full convolution networks, circular neural networks, and production confrontation networks, among which convolutional neural network technology is the most commonly used in pathological image recognition [9].

The accuracy of artificial intelligence and machine learning in the clinical application of pathological diagnosis has been confirmed a lot, and it is feasible for clinical application. For example, the research of Kather et al. shows that the trained classifier can identify the tumor and stroma in colorectal tissue slices, and the accuracy rate is 98.6% [10]. Hu Rong et al. studied the feasibility of artificial intelligence technology based on deep convolutional neural networks to assist in the clinical diagnosis of laryngeal squamous cell carcinoma through deep learning. The results showed that the accuracy, sensitivity, and specificity of AI verification set were 90.91%, 90.12% and 91.53%, which were equivalent to those of experts in otorhinolaryngology, head and neck surgery, with no statistical significance [11].

At present, experiments have confirmed that in most cases, the accuracy of artificial intelligence diagnosis is higher than that of manual diagnosis. For example, in the "Pathological Image Diagnosis Man-Machine Challenge" held during the 7th China Pathology Annual Conference in 2017, only one pathologist was better than artificial intelligence among the 10 pathologists who fought against the artificial intelligence-aided diagnosis machine.

Artificial intelligence pathology can help pathologists solve many problems, but it doesn't replace pathologists. Artificial intelligence can't replace pathologists, but it replaces doctors' repetitive manual labor work, reduces time costs, and allows pathologists to spend more time and energy on medical research.

3. The challenge of digital pathology

Digital pathology is more and more widely used, but it also faces some challenges in clinical application. (1) At present, there is no unified quality control system for digital pathological images. Artificial intelligence diagnosis requires higher digital pathological images, and the quality of digital pathological images directly affects the results of artificial intelligence diagnosis. At present, the performance and quality of different digital scanners are different, the scanned image format is not uniform, and the characteristic information of scanned digital pathological images is not uniform. (2) Lack of high-quality data sets. Artificial intelligence analysis relies on high-quality training data sets, which affect the intelligence level of AI. High-quality training data need to be cleaned and labeled to remove noise. Due to the lack of pathological samples or privacy issues, and manual labeling requires a lot of manpower and time, there is a lack of high-quality data sets for machine learning. (3) Ethical and legal issues to be solved. Whether the results of artificial intelligence diagnosis can be accepted by pathologists, pathologists are faced with ethical and legal issues such as whether they can accept the treatment consequences caused by algorithm deviation [3, 4].

The development of digital pathology is still in its infancy. Although there are some limitations at present, it is believed that in the foreseeable future, there will be a unified digital pathological image quality control system, a large pathological database will be created, and these problems will be solved by carrying out large-scale prospective clinical trials and improving the diagnostic accuracy of artificial intelligence systems. Digital pathology is a subversive technology, that changes the core of pathological processes and is an unstoppable trend.

4. Outlook

Nowadays, digital pathology has become a global trend. According to incomplete statistics, 33%-67% of pathologists around the world are using digital pathology for daily diagnosis. According to Grand View Research, the global digital pathology market will be 767.6 million dollars in 2019, and the compound annual growth rate is expected to be 11.8% by 2027. In the future, the digital pathology market will be large.

At present, China has issued a series of related policies to encourage the development of digital pathology. In February 2017, the National Health and Family Planning Commission issued the Management Specification for Artificial Intelligence-Aided Diagnosis Technology and the Quality Control Index for Clinical Application of Artificial Intelligence-Aided Diagnosis Technology, which standardized the application of artificial intelligence-aided diagnosis and ensured medical treatment and medical safety. At the same time, it is also proposed that artificial intelligence is only used as clinical auxiliary diagnosis and reference, and the final diagnosis result must be determined by qualified clinicians. In March 2022, CMDE (State Food and Drug Administration) issued the Guiding Principles of Medical Device Software Registration and Examination (Revised Edition, 2022), the Notice of Guiding Principles of Artificial Intelligence Medical Device Registration and Examination (No.8, 2022) and the Guiding Principles of Medical Device Network Security Registration and Examination (Revised Edition, 2022), which standardized the management of artificial intelligence medical devices and promoted China.

Some researchers believe that after the digitalization and AI of general practice, the next step of digital pathology will be cloudization, supporting the application of big data in the cloud, transforming pathological work from

individual labor into cluster and collaborative mode, greatly improving work efficiency, alleviating the pressure of insufficient personnel and promoting the birth of a brand-new pathological diagnosis industry.

In the future, with the continuous development of artificial intelligence technology and the continuous improvement of relevant national policies, it will promote intelligent development and more applications of pathological diagnosis and accelerate the development of precision medicine.

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