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Efficacy analysis of acid-fast bacillus detection for tuberculosis by smart medical microscope imaging system

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Background: Tuberculosis is an emerging infectious disease worldwide. The most robust and economical method, recommended by WHO, for first line laboratory diagnosis of pulmonary tuberculosis is acid-fast stain method of sputum smears for acid-fast bacilli (AFB) detection. However, it mostly relies on artificial microscopic examination, which may be tedious. The use of such an automated system may significantly increase the sensitivity of bacilli detection. The objective of this study is to adopt an automated system for identification of AFB under microscope using image recognition technology.

Method: The study was carried out in Kaohsiung Veterans General Hospital, Taiwan. An automated microscope system ("system") (TB-Scan 1.0, Wellgen Medical, Kaohsiung) was used in the TB laboratory. The system consists of two components: (1) Microscopic imaging acquiring hardware with auto-focusing and slide-scanning mechanism to cover the specimen based on WHO recommendation (300 fields with 100x oil immersion); (2) Image recognition software for detection and classification of positive AFB in images. The microscopic images were digitally captured and stored. In the detection phase, candidate AFBs were marked and differentiated from other substances in smear based on color and morphological features. In the classification phase, the feature parameters were extracted from AFB candidates as the input parameters to a proprietary classifier. The result was recorded as positive if any AFB was identified in the image of the slide. We used the results with medical technicians as gold standard in evaluating the system performance. Slides with incomplete stain removal and inconsistent viewing fields were excluded from the study (<3%).

Results: When the system was installed in July 2017, the first test results (from July to September of 2017, n=1,050) was not satisfactory. The sensitivity and specificity were only 13.3% (2/15) and 7.9% (73/925), respectively. After a series of customized imaging training and testing, the second test results (from October to December of 2017, n=2,254) were slightly improved: The sensitivity was 28.8% (34/118) and specificity was 53.8% (1,105/2,053), respectively. However, if technicians can be involved in assisting confirming the images to rule out the false-positives along-side with the automated system, the accuracy, sensitivity and specificity can be further improved to 93.0% (2,096/2,254), 67.8% (137/202) and 98.4% (1,959/1,991), respectively. At manufacturer continuous image training by machine learning algorithms, the performance had incremental improvement. For February 2019 only results (n=448), the accuracy, sensitivity and specificity were stability to 91.7% (411/448), 66.2% (43/65) and 96.3% (368/382), respectively.

Discussion: To our knowledge, this is the first of such automated microscope system for TB smear testing in a control trial. Although the performances of the system still have room for improvement, the following issues are worth considering: (1) Medical technicians as gold standard in this study were applied. The system, for example, detected 135 smears positive for AFB but missed by technicians initially but later the final results were reviewed and retrofitted. The result comparisons (technician vs. culture and system vs. culture) may provide more information about the system's performance; (2) A continuous and customized image training for optimizing recognition performance by machine learning is the key to success. TB smear detection is not "one system fits all" and customized training at each laboratory is essential; (3) The inter-laboratory and intra-laboratory variables could compromise the performance of such system. For example, machine staining would be more consistent compared to manual staining; (4) The objective of the automated system is to increase the test performance and not meant to replace laboratory technicians. Experienced technicians are still needed to further improvement of the system.

Conclusion: Microscopic examination by medical technicians is the last mile of the laboratory automation. We believe such automated microscope system could achieve higher laboratory testing accuracy and efficiency worldwide and may have potential to expand to other medical fields such as gram stains, parasite smear and other smears that require labor-intensive works.

Speaker Biography

Hui-Zin Tu is from Kaohsiung, Taiwan. She received her BS degree from graduated from department of medical laboratory science and biotechnology, Kaohsiung Medicine University and MS degree from National Kaohsiung Normal University, Taiwan. She serves in division of microbiology, department of pathology and laboratory medicine, Kaohsiung Veterans General Hospital for more than 20 years with focus on microbiology, especially in tuberculosis. She has published several peer-reviewed articles in identification of *Mycobacterium tuberculosis* using rapid tests and prevention of false-positive results due to NTM in water by a disposable water filters. Her recent research has focused on improving laboratory sensitivity of acid fast stain on mycobacterial bacilla using AI-driven imaging recognition and automated microscopy.

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