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Validation study of WSI based primary diagnosis by nine Japanese academic institutes

Tomoo Itoh¹, Kazuhiro Tabata² and Ichiro Mori³

¹Kobe University Hospital, Japan

²Nagasaki University Hospital, Japan

³International University of Health and Welfare, Japan

Background: Several reports demonstrate the availability for the primary diagnosis done by digitized slide glass specimen with Whole Slide Imaging (WSI). However, there has been no publication of the validation study from Japan, which is the requirement to obtain approval by Japanese Pharmaceuticals and Medical Devices Agency (PMDA).

Objective: To provide evidence of usability of WSI diagnosis for primary diagnosis compared to conventional glass slide diagnosis by multicenter consortium.

Method: 900 cases, 1070 slides available for histopathologic diagnosis by H&E observation in nine hospitals. The slide glasses were digitized and independent pathologists trained based on CAP guidelines had reviewed and made diagnosis for the digitized cases. Digitization was performed by 20x or 40x optical magnifications utilizing whole slide imaging scanner in each institute and observers reviewed conventional glass slides after more than 2 weeks of washout time interval. Discrepancies between microscope slide and WSI diagnosis were classified into 3 categories; concordance, major discrepancy (defined as ones associated with significant difference in clinical treatment) and minor discrepancy (defined as ones associated with no significant difference in clinical treatment). All pathologists were gathered to review cases with discrepant diagnosis and voted to decide category and cause of discrepancy.

Result: There were 9 diagnoses with major discrepancy (0.8%) and 38 minor diagnoses with discrepancy (3.6%) between WSI and microscopic diagnosis. Eight among 9 diagnoses with major discrepancy were judged as proper to the diagnoses based on conventional microscopic observation. There was no association between level of discrepancy and categories of organ, collecting method or digitized optical magnification. Major discrepancy rates in all institutes were almost similar ranged from 0% to 3.0%.

Conclusion: Our results indicate the safety and efficacy of WSI based primary diagnosis for cases with biopsy and small surgery in Japan. We also emphasize the need of intense training specified for digital pathology diagnosis before its recruitment to the routine clinic.

Biography

Tomoo itoh has completed his PhD at Hokkaido University Graduate School of Medicine and presently he is a Professor and Deputy Director of Diagnostic Pathology at Kobe University Hospital, Japan. He is a board certified Member of the Japanese Society of Pathology and board certified Member of the Japanese Society of Clinical Cytology. He has published more than 34 papers in reputed journals.

tomooitoh@gmail.com

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