USING AI IN CANCER DIAGNOSTICS – MOVING FROM PRECLINICAL TO CLINICAL PRACTICE

Early and accurate diagnosis of cancers is a crucial challenge for clinicians. Many tumor types are difficult to see using standard imaging methods and lab tests do not always aid the accurate diagnosis. Delayed diagnosis often leads to a reduced survival rate which has significant social and economic implications[1]. The applications of AI or artificial intelligence methods in various areas of biomedical research has exponentially increased and one area that is being actively investigated is cancer diagnosis. AI has the ability to process and analyze large complex datasets in a short time period to detect unique patterns that support diagnosis of difficult to detect tumors. Additionally, AI has the potential to screen people with high risk of cancer so that they can benefit from prophylactic treatments[2].

There are a few different types of AI – algorithm based, Machine Learning and Deep Learning[3]. Traditional AI includes algorithms where a computer is trained to perform specific tasks. Machine Learning is another method where an AI model is trained using large datasets to make specific decisions or predictions. The quality of Machine Learning output is dependent on the amount of data used for the training. Deep Learning is the most advanced form of AI where artificial neural networks analyze very large amounts of data. An ideal Deep Learning model is expected to exceed the performance of a human brain.

Over the past few years, researchers have successfully built AI models for cancer diagnosis and classification. In 2018, researchers at the NYU Langone Medical Center developed a Machine Learning model to accurately detect and classify lung adenocarcinoma and small cell lung cancer. The model showed a 97% accuracy which exceeds other available computational models and was trained using over 1,600 tissue slides. Interestingly, the Machine Learning model successfully differentiated between the two common lung cancer types that can be difficult to differentiated by human pathologists[4]. More recently, another group at NYU reported an AI model that was trained using the extremely large NYU Breast Ultrasound Dataset that achieved a higher accuracy score than the average of 10 certified radiologists5. The model showed other benefits as it helped radiologists decrease false positive rates by 37% and reduced the need for biopsies by 27%[5].

These results highlight how much AI methods have advanced but the key question remained – can AI be used in the clinical setting? That question was answered in part by the recent FDA approval of PaigeProstate, an AI pathology product for the *in vitro* diagnostic detection of prostate cancer in biopsy samples[6]. PaigeProstate was developed by an AI company, Paige, that was founded in 2018 based on technology from the Memorial Sloan Kettering Cancer Center. The software scans prostate biopsy slides and identifies cells that have hallmarks of malignancy that are flagged for pathologist review. In order to receive FDA approval, Paige performed a complex clinical study where the product was evaluated by 16 pathologists who scored benign and malignant prostate tissues with and without aid from PaigeProstate. This study was performed on samples from over 150 institutions demonstrating the wide applicability of the product across tissues from various sites. PaigeProstate improved overall detection by about 7% and also reduced false negative and false positive results by 70% and 24% respectively[6]. While PaigeProstate is not a standalone product and is an aid for diagnosis, the significance of the FDA approval is enormous. For the first time, an AI-based diagnostic solution was shown to improve diagnostic accuracy and sensitivity in a large clinical study and it is likely that Paige-Prostate's road to approval will serve as the blueprint for other AI-based products in cancer diagnostics. It is clear that accurate and early cancer diagnoses using AI solutions have started moving from retrospective research studies into clinical practice that will help countless patients live longer.

References:

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