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Study finds startup Paige's cancer pathology algorithms have clinical-grade accuracy

By Stacy Lawrence, Staff Writer

Deep learning algorithms developed at the Memorial Sloan Kettering Cancer Center (MSK) were able to distinguish prostate, skin and breast cancer with nearly perfect accuracy in a recent clinical trial. The technology has already been licensed exclusively by New York-based startup Paige.AI, which snapped up a $25 million series A early last year to continue to advance it.

The latest research was published in the July 15 issue of *Nature Medicine* by Thomas Fuchs, who is the co-founder and CSO of Paige and led the research at his MSK lab. The startup secured a breakthrough device designation from the FDA for an AI-based computational pathology system to detect cancer earlier this year. It's the first AI cancer diagnostic system to receive that designation. (See *BioWorld MedTech*, March 11, 2019.)

AI into the clinic

"The implication for the company and for clinical practice of this study is that this is really the first clinical-grade AI in pathology," said Leo Grady, CEO of Paige. "What that means is that while there have been a lot of studies that have been published before, they were all done using small amounts of data using very contrived scenarios."

"What Thomas and the team were able to show at Memorial Sloan Kettering is that it's now possible with this new technology, to go beyond that research stage and provide a real clinical tool for doctors to help make better decisions about diagnosing and treating patients with cancer," he added.

Grady was previously the SVP of engineering for Redwood City, Calif.-based Heartflow, a private med-tech company that has been valued in excess of $1 billion and integrated its AI-based cardiac disease diagnostic technology via a variety of partnerships with each of the major imaging companies. (See *BioWorld MedTech*, Aug. 30, 2017.)

Heartflow's technology is one of the most prominent examples of AI that's already being systematically integrated into health care, whether or not physicians are aware that machine learning underlies what could be a favored new tool. Grady knows that AI in health care can provide a menacing specter for health care providers, who must balance fears about how such a tool might undermine an established workflow or even eliminate aspects of their own work responsibilities with the potential to enhance their own capabilities and improve patient care.

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Heartflow has focused on demonstrating the potential to improve patient outcomes and reduce costs, rather than emphasizing the AI aspects of the technology. Paige seems likely to follow a similar route, but with the added burden of needing also to routinize the digitization of pathology slides, which is not routinely done at most U.S. hospitals.

"For a doctor or a hospital system, they look at the return on investment for going digital. What they see is that there's a lot of money that you have to spend up front to buy these scanners. Then the savings and improvements that you get from going digital happens a few years down the line. They are hesitant to take that leap because the workflow is new for them," Grady said.

"If you do that same analysis, but you put AI in the mix instead of just going digital, the return on investment becomes really compelling," he continued. "As we build out multiple different indications for multiple different cancer types, that is what's going to drive the wholescale technology for digital pathology."

Further proof

Paige is currently in discussions with the FDA regarding a clinical trial to support a regulatory clearance for its first product. The company declined to disclose a timeline yet for the trial or a subsequent regulatory submission. The initial indication is likely to be an algorithm that helps to ensure that pathologists do not miss prostate cancer diagnoses.

The recent study found that in prostate cancer, basal cell carcinoma and breast cancer metastases to axillary lymph

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nodes the MSK system offered an area under the curve (AUC) of 0.98. That means that 98% of the time it was able to properly distinguish between disease and no disease in all of these types of cancer. That was based on the analysis of a dataset of 44,732 whole slide images from 15,187 patients.

In clinical application, that means a pathologist could exclude roughly 65% to 75% of slides from needing to be analyzed, but still retain 100% sensitivity. “Our results show that this system has the ability to train accurate classification models at unprecedented scale, laying the foundation for the deployment of computational decision support systems in clinical practice,” summed up the paper.

In addition to the MSK study, work to further these efforts has been ongoing within Paige as well. “The publication in *Nature Medicine* of the algorithm developed by Fuchs’ lab is an important milestone for Paige. It demonstrates that AI has the potential to support pathologists in delivering quantitative and more accurate diagnoses, improving treatment for patients worldwide. Leveraging even larger training sets, over the past year, Paige has created novel vendor-agnostic systems that demonstrate even better accuracy,” said Christopher Kanan, lead AI scientist at Paige.

Phenotype to genotype

In the long term, Grady not only anticipates that digital pathology slides and AI analytics will become the norm, but that this technology could offer a better basis to connect the phenotypic presentation of biopsied tissue with the underlying genotypes. That could help researchers and clinicians better understand the operative biological processes and determine treatment in a more precise, individualized fashion.

“There’s so much information in the tissue structure that can help better treat these patients. There are a lot of biomarkers associated with genomic mutations that are associated with different types of cancer that can help doctors make better decisions about what treatment to give these patients, what they’re going to respond to, and ultimately get them better care quicker,” said Grady.

“In the future, we see ourselves as facilitating that entire transformation and providing tools up and down the cancer spectrum in order to not only facilitate and enhance the workflows they’re doing today, but really provide new computational insights into the diagnosis and treatment of these patients,” he concluded. ♦