INFORMATION BRIEF (RAPID REVIEW)

[redacted] - ARTIFICIAL INTELLIGENT (AI) BREAST CANCER

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Medical Development Division
Ministry of Health Malaysia
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Rapid Review
INAHTA

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TITLE: [redacted] - ARTIFICIAL INTELLIGENT (AI) IN BREAST CANCER

PURPOSE

To provide brief information on the efficacy/effectiveness, safety and cost-effectiveness of artificial intelligent (AI) system in breast cancer screening known as [redacted] by [redacted]. The review was requested by the Director of Hospital Putrajaya, Ministry of Health due to propose validation study using local data by the distributor company in Hospital Putrajaya intended as an adjunct tool for physician.

BACKGROUND

[redacted]

[redacted] is an AI radiological computer-assisted detection and software intended to aid in the detection of breast cancer on acquired mammography images. The software detects and identifies suspicious breast cancer cases based on features or information extracted from the images.

EVIDENCE SUMMARY

There was no scientific evidence on [redacted] retrieved from systematic search. However, there were three studies of AI algorithm of breast cancer screening conducted in United States (US) Japan, and Sweden and three summaries of unpublished studies conducted by the developer, provided by the company.

EFFICACY/ EFFECTIVENESS

Schaffer T. et al. conducted diagnostic accuracy study to evaluate whether AI can overcome human mammography interpretation limitations with a rigorous, unbiased evaluation of machine learning algorithms. For development of the AI system algorithm, the study used two data sets; first data set was provided by Kaiser Permanente Washington (KPW) and second data set was from Karolinska Institute (KI) in Sweden. The study and the analysis were conducted between September 2016 and November 2016. The final validation involved data from more than 1,100 participants comprised of 126 teams from 44 countries. Based on the final validation, the top-performing algorithm achieved an AUC of 0.858 (United States) and 0.903 (Sweden) with specificity of 66.2% (United States) and 81.2% (Sweden) at radiologists' sensitivity, lower than community-practice radiologists' specificity of 90.5% (United States) and 98.5% (Sweden). Combining top-performing algorithms and US radiologist assessments

resulted in a higher AUC of 0.942 and achieved a significantly improved specificity (92.0%) at the same sensitivity. According to the authors, while no single AI algorithm outperformed radiologists, an ensemble of AI algorithms combined with radiologist assessment in a single-reader screening environment improved overall accuracy and the potential of using machine learning methods for enhancing mammography screening interpretation.

Another study by Sasaki M. et. al. compared the breast cancer detection performance in digital mammograms of a panel of three unaided human readers versus a stand-alone AI-based Transpara system in a population of Japanese women. According to the authors, the Transpara system has been trained using data from Asian clinics but not Japanese, so they conducted the study to validate the system among Japanese women. The analysis involved 310 Japanese women who underwent mammographic examination between January 2018 and October 2018. The AUC was higher for human readers than with stand-alone Transpara system (human readers 0.816; Transpara system 0.706; difference 0.11; P<0.001). The sensitivity of the unaided human readers for diagnosis was 89% and specificity was 86%. The sensitivity of stand-alone Transpara system for cut-off scores of 4 and 7 were 93% and 85%, and specificities were 45% and 67%, respectively. Although the diagnostic performance of Transpara system was statistically lower than that of human readers, the recent advances in AI algorithms are expected to reduce the difference between computers and human experts in detecting breast cancer.

Another study by Lang K. et. al. investigated whether AI could reduce interval cancer in mammography screening. The study involved 429 women who were diagnosed with interval cancer in Southern Sweden between 2013 and 2017. The mammography data were analysed with a deep learning-based AI system. A statistically significant correlation between interval cancer classification groups and AI risk score was observed ($p < .0001$). AI scored one in three (143/429) interval cancer with risk score 10, of which 67% (96/143) were either classified as minimal signs or false negative. Of these, 58% (83/143) were correctly located by AI, and could therefore potentially be detected at screening with the aid of AI, resulting in a 19.3% (95% CI 15.9–23.4) reduction of interval cancer. At 4% and 1% recall thresholds, the reduction of interval cancer was 11.2% (95% CI 8.5–14.5) and 4.7% (95% CI 3.0–7.1). The corresponding reduction of interval cancer with grave outcome (women who died or with stage IV disease) at risk score 10 was 23% (8/35; 95% CI 12–39). The use of AI in screen reading has the potential to reduce the rate of interval cancer without supplementary screening modalities.

In the document provided, there were summaries which claimed to be validation studies conducted by developer of [redacted] deep-learning AI. Although those summaries reported that the AI systems showed an improvement in screening and diagnosing, further assessment on the unpublished studies could not be done as the full documents were not available.

SAFETY

[redacted] has received Class B Device certification form Medical Device Authority (MDA), Ministry of Health.

No retrievable scientific evidence available on safety of [redacted].

According to a new publication by the World Health Organisation (WHO) on AI for health, the importance of developing the AI systems were establishing AI systems' safety and effectiveness, rapidly making appropriate systems available to those who need them, and fostering dialogue among stakeholders, including developers, regulators, manufacturers, health workers and patients.

COST-EFFECTIVENESS (If any)

No economic evaluation studies on [redacted] were retrieved from scientific databases. No information from the document submitted by the company.

CONCLUSION

[redacted] is an artificial intelligent (AI) tool to assist breast cancer screening. There were limited evidence on AI system in breast cancer screening as well as diagnosing and appeared promising. There was no retrievable evidence on [redacted] to ascertain the benefit of the AI system as an adjunct tool in screening and diagnosing breast cancer. Further research is required.

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