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Validation of Galen Prostate and Galen Breast AI solutions in a Japanese cohort

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BACKGROUND

Prostate and breast cancer incidence rates have risen in Japan, emphasizing the need for precise histopathological diagnosis to determine patient prognosis and guide treatment decisions [1]. Artificial intelligence (AI) algorithms have entered the clinical routine to increase precision and efficacy in patient care with growing malignancy numbers every year [2].

OBJECTIVE

This study aimed to validate the performance and clinical utility of two artificial intelligence (AI) solutions, Galen™ Prostate and Galen™ Breast (Ibex Medical Analytics) in detecting prostate and breast cancer in real-world clinical routine use in a Japanese cohort, also assessing their grading capabilities.

DESIGN

The performance of Galen Prostate [2] and Galen Breast [3] was evaluated based on the concordance between the initial clinical diagnoses at Kameda Medical Center (KMC) and the AI results at the case level.

Core needle biopsy cases: Prostate (100), Breast (100) | **Slides:** Prostate (741), Breast (678)

Prostate
- AdC vs. Benign
- ASAP/AdC/Other cancer vs. Benign
- Gleason Score
- Perineural Invasion

Breast
- Invasive Cancer vs. Benign/DCIS/ADH
- DCIS vs. benign
- LVIs

Concordance
Initial clinical diagnoses | Galen Prostate/Galen Breast

AdC (Adenocarcinoma) | ASAP (atypical small acinar proliferation | ADH (atypical ductal hyperplasia) | LVI (lymphovascular invasion) | DCIS (Ductal carcinoma in situ)

RESULTS

5 cases were revised following Galen Prostate alerts, including changes from benign to malignant (n=1) and higher Gleason score (n=4).

Galen Prostate detected perineural invasion in **9** additional cases, which were not initially reported (Fig 3).

100% of the invasive cancers (n=45) were detected by the Galen Breast in the breast cohort and assigned medium to high risk (Fig 2).

Moreover, all 3 LVI were detected by Galen Breast, **2** of which were not initially clinically diagnosed (Fig 4).

Table 1 | Performace of the AI solutions

Tissue	Analysis	AUC	Sensitivity	Specificity
Prostate	AdC vs. Benign	0.988	96.7%	93.9%
	ASAP/AdC/Other cancer vs. Benign	0.969	92.3%	88.6%
	medium/high (Gleason 7 and higher) vs. low-grade AdC	0.994	97.9%	92.9%
Breast	Invasive cancer vs. Benign/DCIS/ADH	0.997	97.8%	98.1%
	DCIS vs. benign	0.996	100%	93.8%

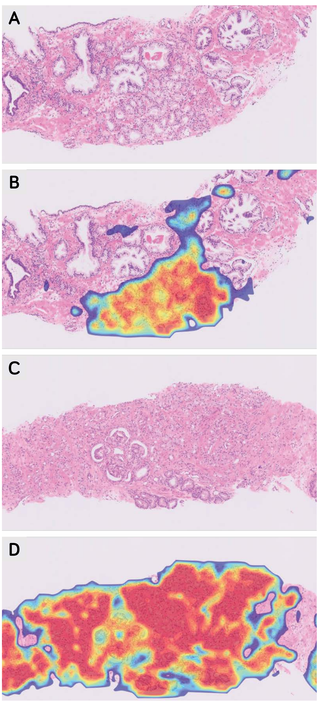

Figure 1 | Examples of prostate cases initially diagnosed as cancer with concomitant high cancer score by the Galen Prostate. (A) A core biopsy diagnosed as Gleason score 3+3=6; (B) Galen Prostate prediction showing cancer heatmap with high probability on the center of the lesion; (C) A core biopsy diagnosed as Gleason score 4+3=7; (D) Galen Prostate prediction showing cancer heatmap with almost exclusively high probability

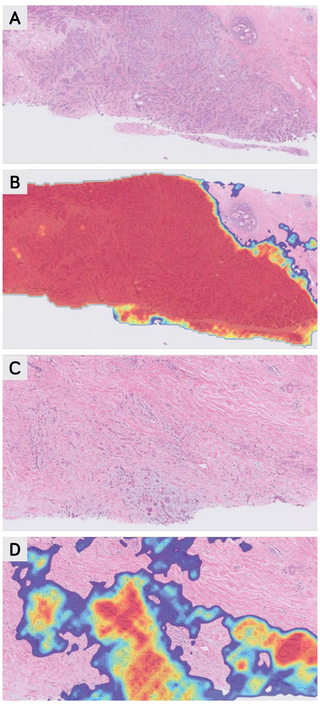

Figure 2 | Examples of breast cases initially diagnosed as invasive cancer with concomitant high invasive cancer score by the Galen Breast. (A) A core biopsy diagnosed as invasive breast cancer of no special type; (B) Same core with Galen Breast prediction showing high probability of invasive cancer, not including the DCIS lesion area. (C) A core biopsy diagnosed as invasive lobular carcinoma; (D) Same core with Galen Breast prediction showing high probability of invasive cancer toward the center of the lesion

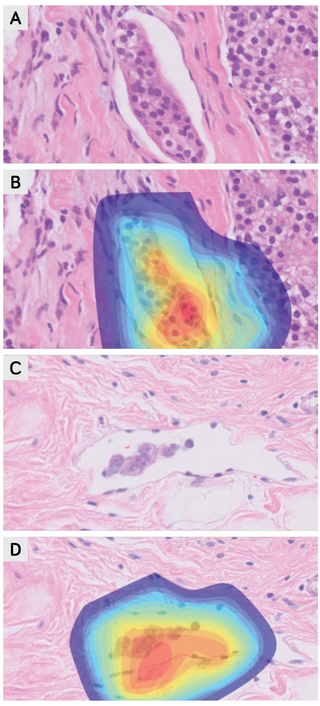

Figure 3 | Examples of lymphovascular invasions detected by the Galen Breast, previously unreported in the initial diagnosis (A, B, C, and D). All images are at 20x magnification (0.5µm/pixel), stained with hematoxylin and eosin

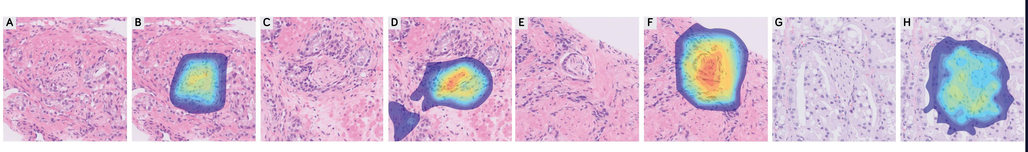

Figure 4 | Examples of tumor perineural invasion detected by the Galen Prostate, previously unreported in the initial diagnosis

CONCLUSIONS

This study demonstrated high accuracy of these AI solutions irrespective of the geographical origin and different lab pre-analytics.

This study paves the way for broader adoption of AI as decision support tools within the Asian population, potentially leading to improved patient outcomes and decreased healthcare costs.

References | [1] Cancer Statistics. Cancer Information Service, National Cancer Center, Japan. 2023. 03/01/2023]; Available from: https://ganjoho.jp/reg_stat/statistics/data/dl/index.html#a14.

[2] Pantanowitz, L., et al. The Lancet Digital Health, 2020. 2(8): p. e407-e416. [3] Sandbank, J., et al. NPJ Breast Cancer, 2022. 8(1): p. 129.

Disclosures | The Authors declare no Competing Non-Financial Interests but the following Competing Financial Interests: CL is an author on pending patents US 62/743,559 and US 62/981,925 (including System & Methods for Personalization and Optimization of Digital Pathology Analysis and System and Method of Managing Workflow of Examination of Pathology Slides). All the other authors declare no Competing Financial or Non-Financial Interests.