



#AHA24

# **ARTIFICIAL INTELLIGENCE-BASED AUTOMATED ECHOCARDIOGRAPHIC MEASUREMENTS AND THE WORKFLOW OF SONOGRAPHERS: RANDOMIZED CROSSOVER TRIAL (AI-ECHO RCT)**

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# DISCLOSURES

- This study was not funded by US2.ai or any other commercial companies. US2.ai and M3AI Inc. provided the AI software but did not offer financial support.
- Dr. Kagiya has received research grants from EchoNous Inc., AMI Inc., AstraZeneca, and Bristol Myers Squibb; speaker honoraria from Eli Lilly, Novartis Japan, Otsuka Pharmaceutical, and Boehringer-Ingelheim outside this work; and is affiliated with a department funded by Paramount Bed Ltd.
- The other authors have no conflicts of interest to declare.

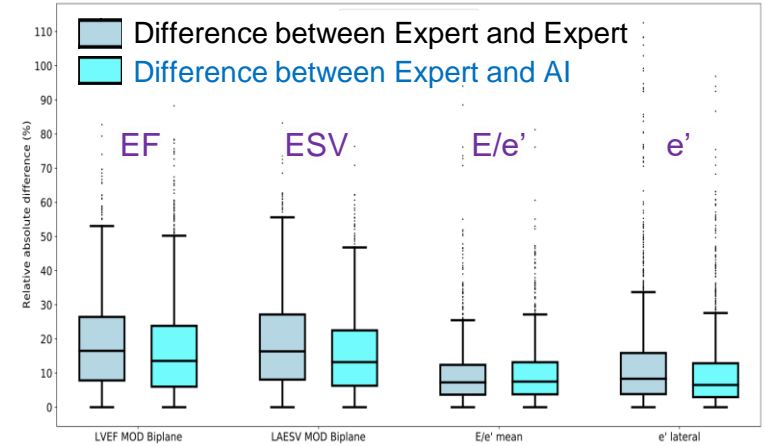


# BACKGROUND 1

- Echocardiography is a cornerstone diagnostic tool in cardiovascular (CV) medicine, widely used for its detailed insights into cardiac structure and function.
- However, increasing demand for echocardiography has placed a substantial burden on echocardiographic laboratories, especially in Japan, where 3.5 times more exams per capita are performed compared to the USA.
- The rapid advancement of artificial intelligence (AI) has enabled automated analysis of echocardiograms.



## Expert-level analysis of most params



# BACKGROUND 2

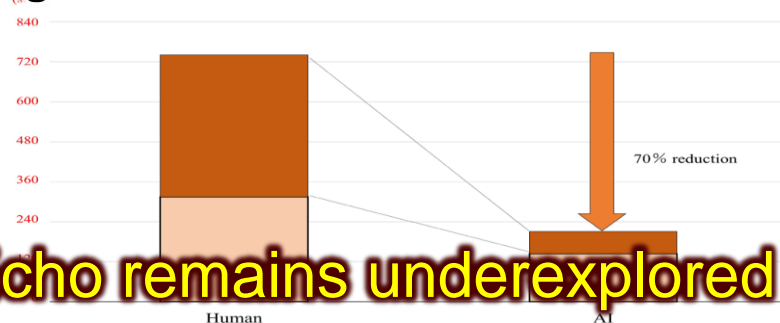
Fully-automatic analysis of > 70 parameters

Editable trace lines ensuring tracing accuracies

First name, Last name, Patient id	Exact search No	Report	Flag	Exam date	Gender	Birth date	Approved	Visits
1^	00084334-02	Done	Yes	Dec 22, 2023	M	Jan 1, 1975	No	2
SHIYUUNOU^	0000005292	Done	No	Dec 22, 2023	F	May 18, 1976	No	1
0001	0000005238	Done	No	Nov 17, 2021	M	Jan 1, 1940	No	1
NA	0000005238	Done	No	Dec 9, 2023	M	Sep 15, 1942	No	1
5238^	0000005238	Done	No	Dec 9, 2023	M	Sep 15, 1942	No	1
20231208191231	31121920231208	Done	No	Dec 9, 2023			No	1
Cc	12345	Done	No	Sep 10, 2021			No	1

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## Significant reduction in examination time



The real-world clinical utility of AI-Echo remains underexplored



# OBJECTIVES

- To investigate the impact of AI-based echocardiographic automation on workflow efficiency in real-world clinical settings.

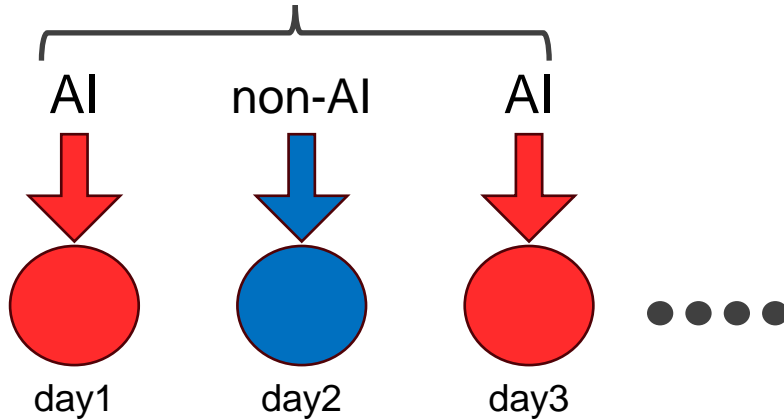


# METHODS

## STUDY DESIGN

### Randomized cross-over trial

Randomly assigned on a daily basis



*Sample size calculation:*

Assumed a 20% increase in exam numbers

$\alpha$  0.05,  $\beta$  0.8, 10% safety margin  $\rightarrow$  38 days in total

### ➤ Participants

Four sonographers who perform “screening” echocardiography for CV risk assessment

### ➤ Intervention

*AI day:*

A sonographer scans, AI measures, the sonographer checks AI’s values, and an echo doctor checks and approves the report

*Non-AI days:*

A sonographer scans, measures, and an echo doctor checks and approves the report



# ENDPOINTS

## Primary endpoints

Examination efficiency:

- Examination time
- Number of exams by a sonographer per day

Non-AI day  
(normal workflow)



VS

AI day  
(AI measure /  
human check)



## Secondary endpoints

- Number of echocardiographic parameters analyzed per examination
- Sonographers' fatigue, self-reported using a daily questionnaire
- Quality of echocardiographic images
- AI's performance: concordance between AI's initial values and expert-endorsed final values



# RESULTS

## SCANNING CHARACTERISTICS

	Non-AI day (19 days)	AI day (19 days)
N of reports	N = 268	N = 317
Female, n (%)	144 (54%)	191 (60%)
Age, yr	64 ± 16	65 ± 15
Body mass index	22.9 ± 3.8	23.2 ± 4.4
ECG, n (%)		
Sinus rhythm	250 (93%)	311 (98%)
Atrial fibrillation	10 (3.7%)	4 (1.3%)
LVIDd, mm	44 ± 5	44 ± 5
LVIDs, mm	29 ± 4	28 ± 5
IVSTd, mm	9 ± 2	9 ± 2
LVEF (2D disk), %	63 ± 8	64 ± 8
LA diameter, mm	34 ± 7	34 ± 6
* Aortic stenosis, n (%)	1 (0.4%)	4 (1.3%)
* Aortic regurgitation, n (%)	12 (4.5%)	8 (2.5%)
* Mitral regurgitation, n (%)	4 (1.5%)	5 (1.6%)

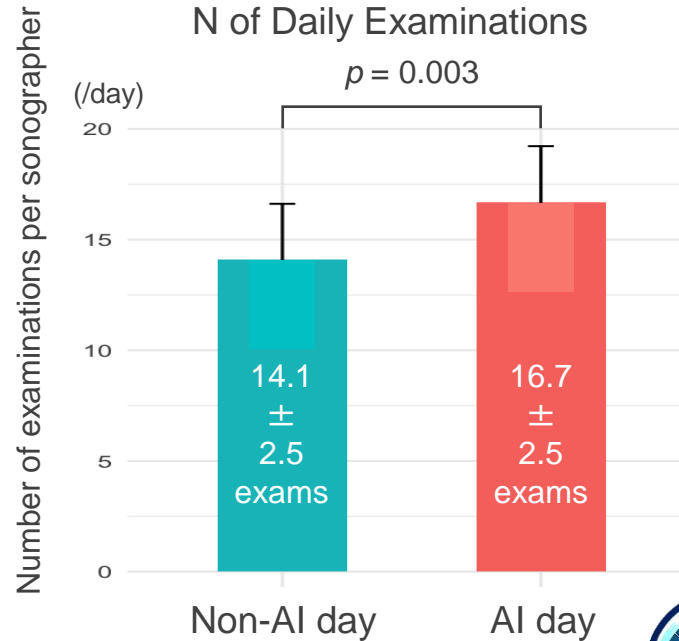
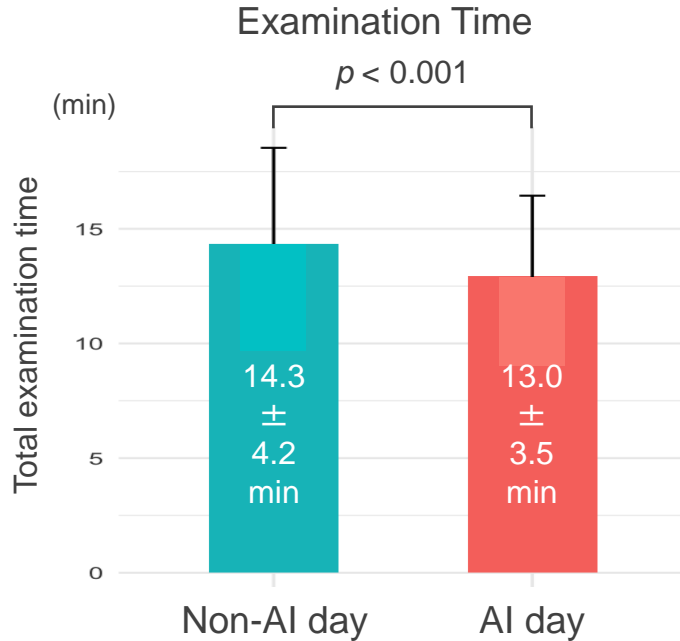
\* Moderate or severe degrees





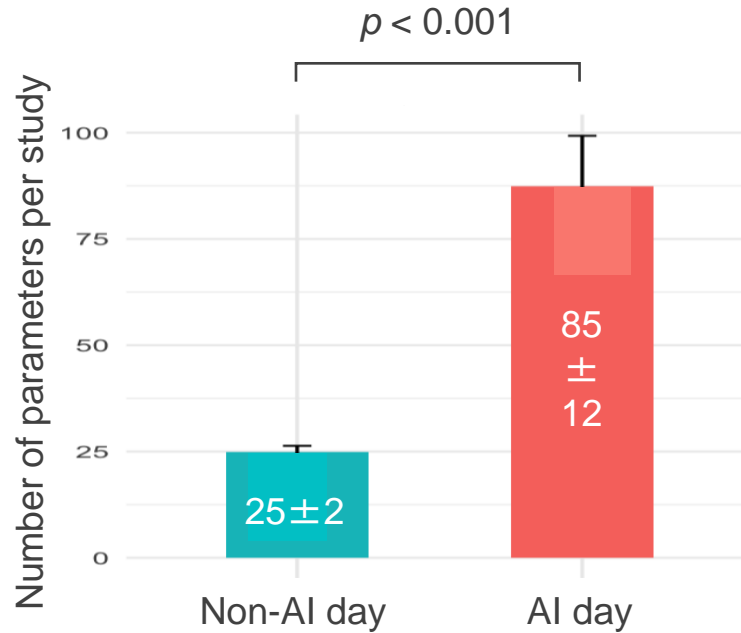
# PRIMARY ENDPOINTS

## Efficiency of echocardiographic examinations



# NUMBER OF ANALYZED PARAMETERS

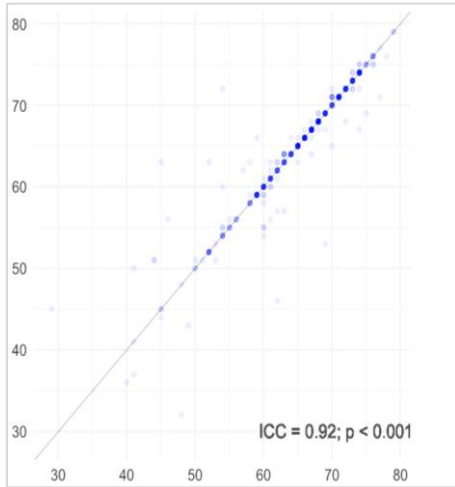
3.4-fold increase in the number of echocardiographic parameters



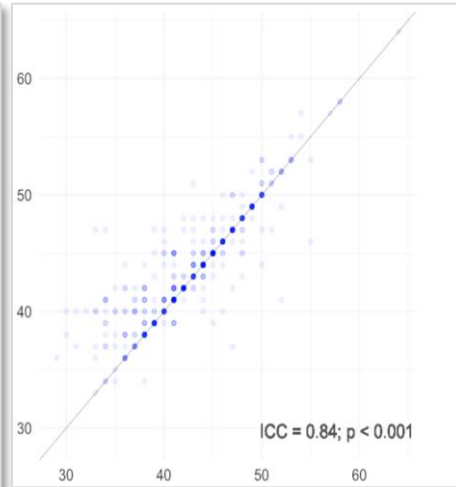
# AI'S ACCURACY IN THE REAL WORLD

Concordance between AI's initial values & final report values

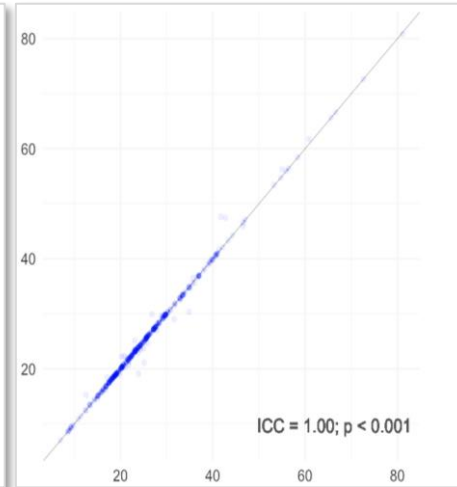
LVEF (2D Disk)



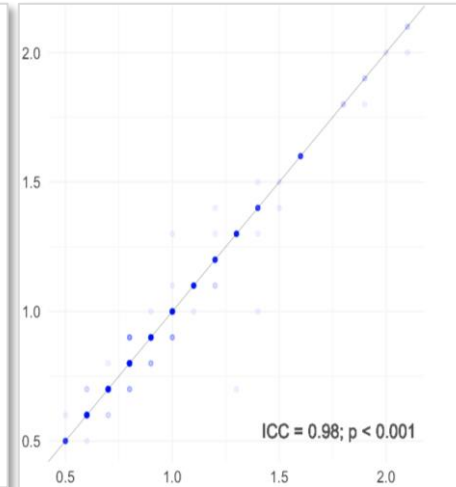
LVIDd



LAVI



E/A



# AI'S ACCURACY IN THE REAL WORLD

	Number of studies that AI could return the value	Acceptance rate of AI's values*, %	Mean absolute modification by sonographers
IVSTd, mm	313 (99.1%)	94.6%	1.7 mm
LVIDd, mm	314 (99.4%)	86.7%	3.4 mm
LVIDs, mm	311 (98.4%)	70.6%	3.9 mm
LVEDV, ml	279 (93.3%)	94.3%	8.0 ml
LVESV, ml	279 (93.3%)	92.0%	5.2 ml
LVEF (2D disk), %	279 (93.3%)	91.3%	3.9%
MV-E, cm/s	262 (83.4%)	95.2%	4.8 cm/s
MV-A, cm/s	249 (83.6%)	96.3%	3.1 cm/s
E/A	244 (81.9%)	99.0%	0.1
e' (septal), cm/s	306 (96.8%)	94.9%	0.5 cm/s
E/e' (septal)	255 (80.7%)	91.8%	0.6
TR Vmax, m/s	260 (95.6%)	94.9%	0.3 m/s
LAVI, ml/m <sup>2</sup>	246 (85.1%)	98.6%	0.7 ml/m <sup>2</sup>
TAPSE, mm	135 (99.3%)	98.5%	0.7 mm

\* Rate at which AI's values were within the clinically acceptable range of final report values



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# MENTAL FATIGUE OF SONOGRAPHERS

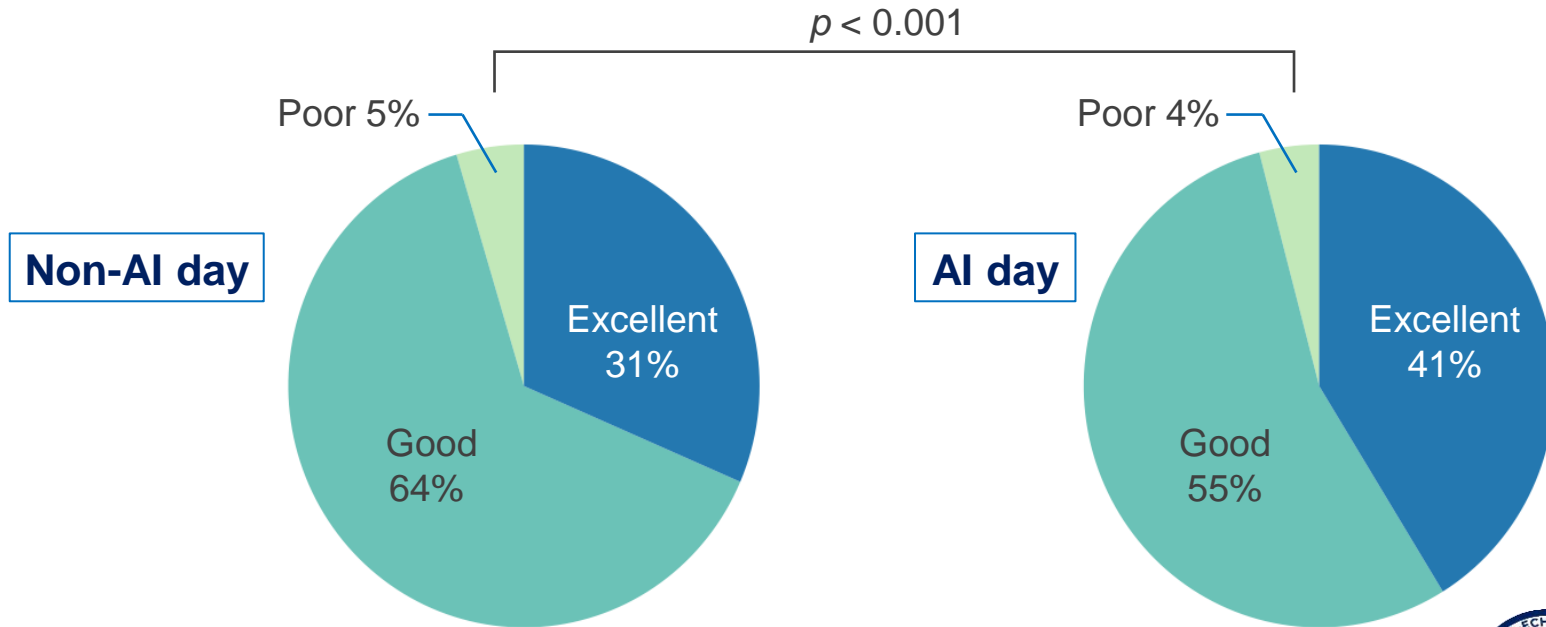
Evaluated at the end of each study day with a five-point Likert scale

	Non-AI days	AI days	p-value
Mental fatigue	4.7 ± 0.6	4.1 ± 1.1	0.039
Physical fatigue	4.5 ± 0.8	4.0 ± 0.9	0.088
Perception of task complexity	4.2 ± 0.8	3.7 ± 1.0	0.21



# IMAGE QUALITY BY BLINDED REVIEWERS

Assessed with a 3-point scale on five standard views: LAX, SAX, A4C, A3C, and A2C



# DISCUSSION

- This was the first prospective, real-world randomized study in AI-assisted echocardiography versus standard workflow.
- AI improved echocardiography efficiency, reducing exam time and increasing the number of daily exams.
- Despite the increased number of exams and parameters analyzed, the sonographers' mental fatigue was actually mitigated.
- Such workflow improvements may help sonographers engage in more human-centered and clinically enriching tasks, such as discussing diagnoses and treatments, potentially enhancing job satisfaction.



# LIMITATIONS

- Double-blinding was infeasible, as sonographers were required to actively use the AI tool, and the 3.4-fold increase in parameters made it impossible to blind cardiologists. However, the evaluators and analysts were blinded to the assignments and results.
- The single-center design and short study duration limit the generalizability and long-term applicability. Additionally, "screening" echocardiography for patients without known cardiovascular disease may be less common in other countries.
- The study assessed workflow efficiency but did not evaluate patient outcomes.



# CONCLUSIONS

- We conducted the first randomized trial to evaluate AI-based automated analysis within a real-world clinical echocardiography workflow.
- The AI-based automated analysis system improved examination efficiency and quality without increasing sonographers' fatigue.



# THANK YOU

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