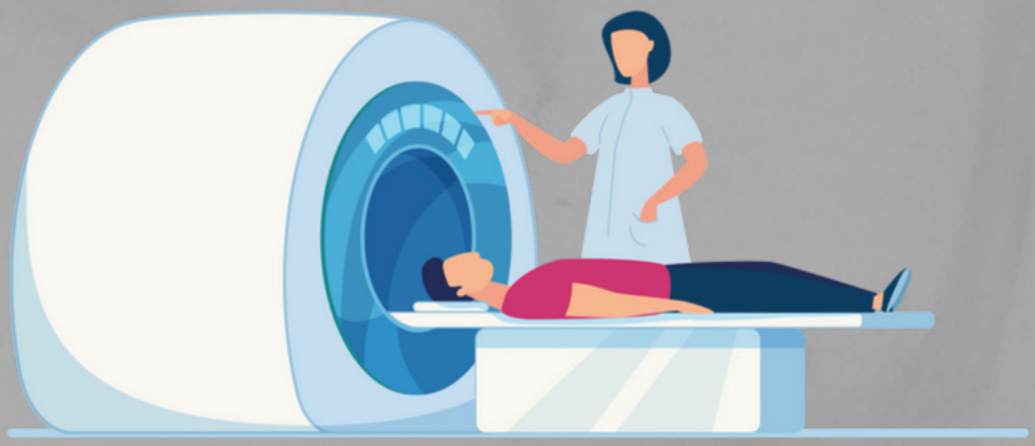
HeartLung
Technologies

Opportunistic Osteoporosis Screening with

AutoBMD™ AI

CT Add-on Automated Bone Mineral Density Reports



APPROVED FDA APPROVED

AutoBMD™ AI Improves Patient Care and Bottom Line

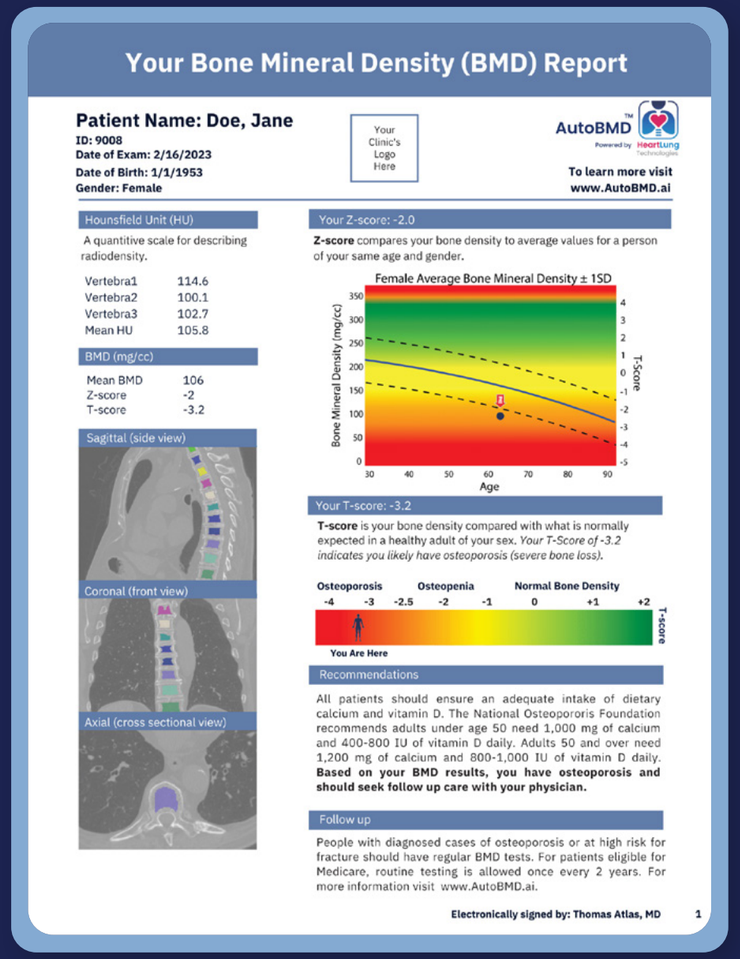
How To Order AutoBMD™

AutoBMD™ for Diagnostic Imaging Centers

Step 1: Set up your HeartLung Provider account in less than 5 minutes

Step 2: Install HeartLung Gateway to send scans to AutoBMD™ cloud automatically

Step 3: Access AutoBMD™ Reports on your Provider Portal and Opt-in to automatic forwarding reports to patients



Your Bone Mineral Density (BMD) Report

Patient Name: Doe, Jane
ID: 9008
Date of Exam: 2/16/2023
Date of Birth: 1/1/1953
Gender: Female

Your Clinic's Logo Here

AutoBMD™ Powered by HeartLung Technologies
To learn more visit www.AutoBMD.ai

Hounsfield Unit (HU)

A quantitive scale for describing radiodensity.

Vertebra1	114.6
Vertebra2	100.1
Vertebra3	102.7
Mean HU	105.8

BMD (mg/cc)

Mean BMD	106
Z-score	-2
T-score	-3.2

Sagittal (side view)

Coronal (front view)

Axial (cross sectional view)

Your Z-score: -2.0

Z-score compares your bone density to average values for a person of your same age and gender.

Female Average Bone Mineral Density ± 1SD

Bone Mineral Density (mg/cc) 350 300 250 200 150 100 50 0

T-Score 4 3 2 1 0 -1 -2 -3 -4 -5

Age 30 40 50 60 70 80 90

Your T-score: -3.2

T-score is your bone density compared with what is normally expected in a healthy adult of your sex. *Your T-Score of -3.2 indicates you likely have osteoporosis (severe bone loss).*

Osteoporosis | Osteopenia | Normal Bone Density

-4 -3 -2.5 -2 -1 0 +1 +2 T-score

You Are Here

Recommendations

All patients should ensure an adequate intake of dietary calcium and vitamin D. The National Osteopororis Foundation recommends adults under age 50 need 1,000 mg of calcium and 400-800 IU of vitamin D daily. Adults 50 and over need 1,200 mg of calcium and 800-1,000 IU of vitamin D daily. **Based on your BMD results, you have osteoporosis and should seek follow up care with your physician.**

Follow up

People with diagnosed cases of osteoporosis or at high risk for fracture should have regular BMD tests. For patients eligible for Medicare, routine testing is allowed once every 2 years. For more information visit www.AutoBMD.ai.

Electronically signed by: Thomas Atlas, MD 1

How AutoBMD™ Works

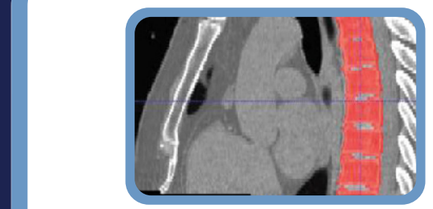
Step 1:
Automatically detecting the vertebral column

Step 2:
Disk segmentation and labeling vertebral bones

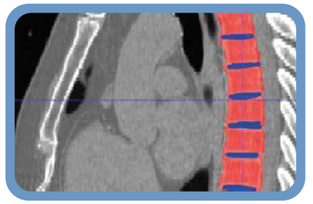
Step 3:
Detecting the trabecular compoent of the vertebral bones as the region of interest

Step 4:
Calculating BMD using HU units with built-in calibration factor (no phantom required)

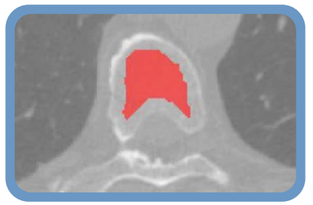
Step 5:
Reporting T-Score and Z-Score along with axial, coronal, and sagittal views of the ROI



Spine Localization

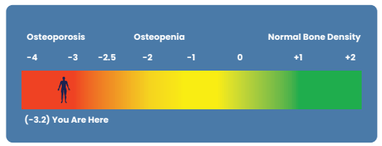


Disk Segmentation



Tebecular Bone Identification

BMD Measurement



AutoBMD™ AI

HeartLung.AI

Our Approach Is Opportunistic Bone Mineral Density

It is superior to DEXA and regular QCT scans

No Extra Scan
No Extra Radiation
No Extra Trip To Radiology Clinics
Extra Value for Patients
Extra Revenue for Clinics

AutoBMD™ enables your doctor to take advantage of CT scans ordered for other purposes and measure your bone density.

Low Bone Density
is a condition that causes bone mineral density to decline, increasing risk of fractures.

How It's Detected

Bone density is usually measured using a DEXA scan or quantitative CT scan (QCT)

DEXA Scan CT Scan

AutoBMD™ uses QCT but does not require a new scan. It takes advantage of existing CT scans.

HeartLung's AutoBMD™ is the first and only FDA-approved AI-enabled bone densitometry with "opportunistic screening" indication that is DEXA-equivalent and works both on thoracic and abdominal & pelvic CT scans.

AutoBMD™ AI

HeartLung.AI

Direct and Indirect Revenue Opportunities for Providers

Imaging Centers
Direct Revenue

Hospitals
Indirect Revenue

Opportunistic Radiation-Free Osteoporosis Screening With FDA-Approved AI-Enabled AutoBMD™										
AutoBMD™ Direct Revenue Analysis										
Assumptions:										
	Start-Up Cost								**$0**	
	Cost Per AutoBMD Report								**$30**	
CPT 77078 Reimbusement:									**$103**	
Net Revenue Per AutoBMD Report:									**$73**	
Return on Investment										
	Scans/Day		5	10	20	30	50	70	100	
	Monthly Revenue		$8,050.90	$16,101.80	$32,203.60	$48,305.40	$80,509.00	$112,712.60	$161,018.00	
	Annual Revenue		**$96,611**	**$193,221.60**	**$386,443.20**	**$579,665**	**$966,108**	**$1,352,551**	**$1,932,216**	
5 Year Revenue Projection			**$483,054**	**$966,108**	**$1,932,216**	**$2,898,324**	**$4,830,540**	**$6,762,756**	**$9,661,080**	

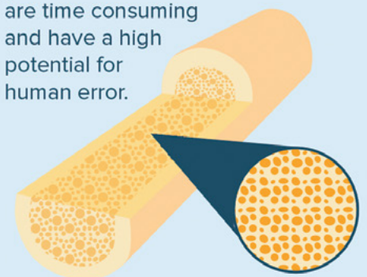
AutoBMD™ Indirect/Downstream Revenue Analysis								
Assumptions:								
	Osteopenia/Osteporosis (Will Need DEXA Every 1-2 Years)						**35%**	
	Endocrine Clinic Visit for Treatment (1-2 Visits a Year)						**35%**	
	Orthopedic Procedures Over Next 5 Years						**10%**	
Downstream Revenue								
Number of Scans per Year		1,320	2,640	5,280	7,920	13,200	18,480	26,400
5Yr DEXA Revenue	($55/case/Yr)x2	**$50,820**	**$101,640**	**$203,280**	**$304,920**	**$508,200**	**$711,480**	**$1,016,400**
5Yr Endocrine Revenue	($75/visit/Yr)x2	**$69,300**	**$138,600**	**$277,200**	**$415,800**	**$693,000**	**$970,200**	**$1,386,000**
5Yr Orthopedic Revenue	($5,000/case)	**$660,000**	**$1,320,000**	**$2,640,000**	**$3,960,000**	**$6,600,000**	**$9,240,000**	**$13,200,000**
Total 5Yr Revenue Projection		**$780,120**	**$1,560,240**	**$3,120,480**	**$4,680,720**	**$7,801,200**	**$10,921,680**	**$15,602,400**

AutoBMD™ AI

Visual Abstract

How well does an artificial intelligence (AI) tool measure thoracic vertebral bone mineral density (BMD) in non-contrast cardiac CT scans used for coronary artery calcium scoring (CAC)?

A BMD test is the only way to detect osteoporosis and osteopenia early, yet manual measurements of BMD are time consuming and have a high potential for human error.



Trained a deep learning model to detect vertebral bodies, intervertebral discs, and trabecular components of the vertebral body

Compared to previous cases with manual BMD measurements

Auto BMD	166.3 ± 47.9 g/cm3
Manual BMD	163.1 ± 46.0 g/cm3

Auto BMD and Manual BMD measurement were not significantly different

Number of reports an AI-enabled AutoBMD can generate in the time it takes a human to analyze and report one case

AutoBMD is an FDA approved AI-enabled opportunistic tool that accurately detects osteoporosis and osteopenia in CAC scans. AutoBMD is promising as a novel screening tool with no additional radiation and no separate CT scan.

JACR VISUAL ABSTRACT

Journal of American College of Radiology 2024 Apr;21(4):624-632

Take Home Points

- AI-enabled AutoBMD™ can measure BMD in patients with accuracy comparable to manual measurements by radiologists.
- Automated methods of measuring BMD are much faster on average compared with manual methods of measuring BMD (15 seconds versus 5.5 min).
- The incremental value of AutoBMD™ for individuals undergoing Coronary Artery Calcium (CAC) scans is as promising as a novel screening tool with no additional radiation and no separate CT scan.

Scientific Publications

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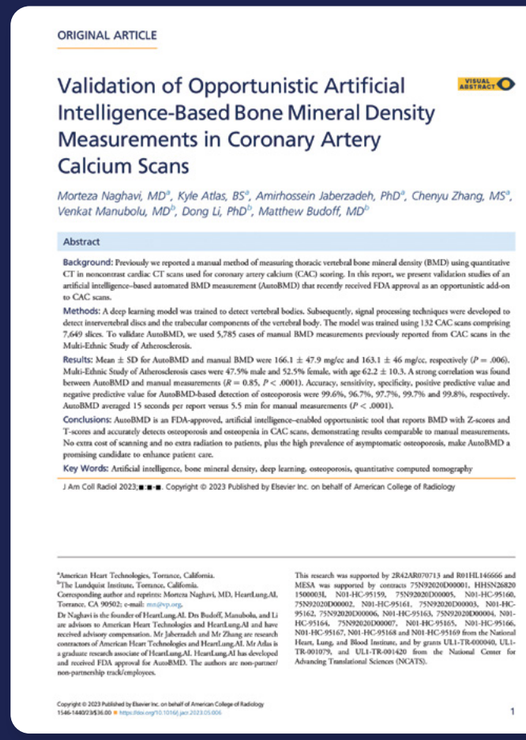

ORIGINAL ARTICLE

Validation of Opportunistic Artificial Intelligence-Based Bone Mineral Density Measurements in Coronary Artery Calcium Scans

Morteza Naghavi, MD[a], Kyle Atlas, BS[a], Amirhossein Jaberzadeh, PhD[a], Chenyu Zhang, MS[a], Venkat Manubolu, MD[b], Dong Li, PhD[b], Matthew Budoff, MD[b]

Abstract

Background: Previously we reported a manual method of measuring thoracic vertebral bone mineral density (BMD) using quantitative CT in noncontrast cardiac CT scans used for coronary artery calcium (CAC) scoring. In this report, we present validation studies of an artificial intelligence–based automated BMD measurement (AutoBMD) that recently received FDA approval as an opportunistic add-on to CAC scans.

Methods: A deep learning model was trained to detect vertebral bodies. Subsequently, signal processing techniques were developed to detect intervertebral discs and the trabecular components of the vertebral body. The model was trained using 132 CAC scans comprising 7,649 slices. To validate AutoBMD, we used 5,785 cases of manual BMD measurements previously reported from CAC scans in the Multi-Ethnic Study of Atherosclerosis.

Results: Mean ± SD for AutoBMD and manual BMD were 166.1 ± 47.9 mg/cc and 163.1 ± 46 mg/cc, respectively ($P = .006$). Multi-Ethnic Study of Atherosclerosis cases were 47.5% male and 52.5% female, with age 62.2 ± 10.3. A strong correlation was found between AutoBMD and manual measurements ($R = 0.85$, $P < .0001$). Accuracy, sensitivity, specificity, positive predictive value and negative predictive value for AutoBMD-based detection of osteoporosis were 99.6%, 96.7%, 97.7%, 99.7% and 99.8%, respectively. AutoBMD averaged 15 seconds per report versus 5.5 min for manual measurements ($P < .0001$).

Conclusions: AutoBMD is an FDA-approved, artificial intelligence–enabled opportunistic tool that reports BMD with Z-scores and T-scores and accurately detects osteoporosis and osteopenia in CAC scans, demonstrating results comparable to manual measurements. No extra cost of scanning and no extra radiation to patients, plus the high prevalence of asymptomatic osteoporosis, make AutoBMD a promising candidate to enhance patient care.

Key Words: Artificial intelligence, bone mineral density, deep learning, osteoporosis, quantitative computed tomography

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- Naghavi M, Atlas K, Jaberzadeh A, Zhang C, Manubolu V, Li D, Budoff M. Validation of Opportunistic Artificial Intelligence-Based Bone Mineral Density Measurements in Coronary Artery Calcium Scans. J Am Coll Radiol. 2024 Apr;21(4):624-632.

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Opportunistic AI-enabled automated bone mineral density measurements in lung cancer screening and coronary calcium scoring CT scans are equivalent

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Osteopenia
Cardiovascular Screening
Lung cancer screening

ABSTRACT

Rationale and objectives: We previously reported a novel manual method for measuring bone mineral density (BMD) in coronary artery calcium (CAC) scans and validated our method against Dual X-Ray Absorptiometry (DEXA). Furthermore, we have developed and validated an artificial intelligence (AI) based automated BMD (AutoBMD) measurement as an opportunistic add-on to CAC scans that recently received FDA approval. In this report, we present evidence of equivalency between AutoBMD measurements in cardiac vs lung CT scans.
Materials and methods: AI models were trained using 132 cases with 7649 (3 mm) slices for CAC, and 37 cases with 21918 (0.5 mm) slices for lung scans. To validate AutoBMD against manual measurements, we used 6776 cases of BMD measured manually on CAC scans in the Multi-Ethnic Study of Atherosclerosis (MESA). We then used 165 additional cases from Harbor UCLA Lundquist Institute to compare AutoBMD in patients who underwent both cardiac and lung scans on the same day.
Results: Mean±SD for age was 69 ± 9.4 years with 52.4% male. AutoBMD in lung and cardiac scans, and manual BMD in cardiac scans were 153.7 ± 43.9, 155.1 ± 44.4, and 163.6 ± 45.3 g/cm^3, respectively ($p = 0.09$). Bland-Altman agreement analysis between AutoBMD lung and cardiac scans resulted in 1.37 g/cm^3 mean differences. Pearson correlation coefficient between lung and cardiac AutoBMD was $R^2 = 0.95$ ($p < 0.0001$).
Conclusion: Opportunistic BMD measurement using AutoBMD in CAC and lung cancer screening scans is promising and yields similar results. No extra radiation plus the high prevalence of asymptomatic osteoporosis makes AutoBMD an ideal screening tool for osteopenia and osteoporosis in CT scans done for other reasons.

1. Introduction

Global deaths, and DALYs (disability-adjusted life-years) attributable to low bone mineral density (BMD) increased from 207,367 and 8568,936 in 1990 to 437,804 and 16,647,466 in 2019, an increase of 111.16% and 93.82%, respectively [1]. More than 10 million Americans over the age of 50 are currently affected by osteoporosis and another 44 million have low BMD, also known as osteopenia [2]. Osteoporotic individuals are usually asymptomatic and unaware of their condition prior to experiencing a fracture, therefore screening for osteoporosis is recommended by US Preventive Services Task Force [3]. With appropriate treatment, about half of all osteoporosis-related repeat fractures can be prevented [4]. The only way to identify these individuals prior to the occurrence of a fracture and apply appropriate treatment to prevent further bone loss is through a BMD screening test [5].

Dual-energy x-ray absorptiometry (DEXA) is the current clinical imaging standard for assessing BMD [3]. However, only one out of five people who should get a DEXA scan actually get one [6]. Additionally,

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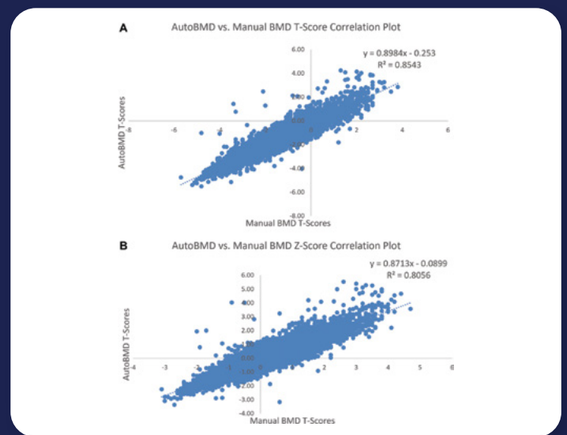
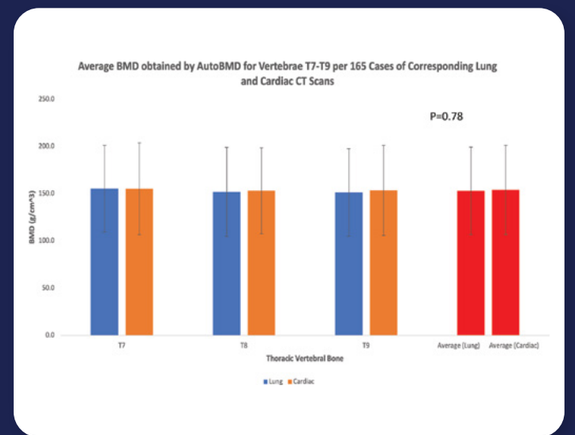
- Naghavi M, De Oliveira I, Mao SS, Jaberzadeh A, Montoya J, Zhang C, Atlas K, Manubolu V, Montes M, Li D, Atlas T, Reeves A, Henschke C, Yankelevitz D, Budoff M. Opportunistic AI-enabled automated bone mineral density measurements in lung cancer screening and coronary calcium scoring CT scans are equivalent. Eur J Radiol Open. 2023 May 13;10:100492.



- AutoBMD results obtained for the average BMD for vertebrae T7 to T9 in 165 corresponding lung and cardiac CT scans. For all vertebrae, n = 165, with the exception of T9 for cardiac for which n = 150.



- (a) T-score correlation plot of AutoBMD software and manual bone mineral density (BMD) (R2 ¼ 0.85). (b) Z-score correlation plot of AutoBMD software and manual BMD (R2 ¼ 0.80).

AutoBMD™ AI

Scientific Publications

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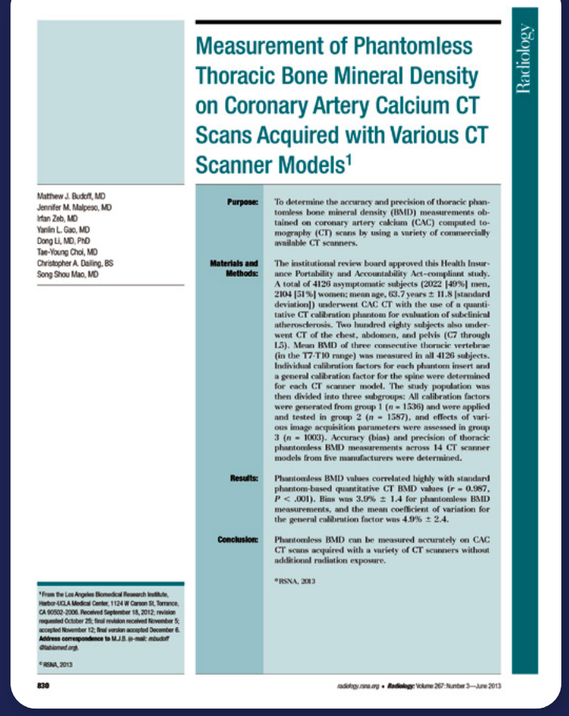


Measurement of Phantomless Thoracic Bone Mineral Density on Coronary Artery Calcium CT Scans Acquired with Various CT Scanner Models[1]

Radiology

Matthew J. Budoff, MD
Jennifer M. Malpeso, MD
Irfan Zeb, MD
Yanlin L. Gao, MD
Dong Li, MD, PhD
Tae-Young Choi, MD
Christopher A. Dailing, BS
Song Shou Mao, MD

Purpose: To determine the accuracy and precision of thoracic phantomless bone mineral density (BMD) measurements obtained on coronary artery calcium (CAC) computed tomography (CT) scans by using a variety of commercially available CT scanners.

Materials and Methods: The institutional review board approved this Health Insurance Portability and Accountability Act–compliant study. A total of 4120 asymptomatic subjects (2022 [49%] men, 2104 [51%] women; mean age, 63.7 years ± 11.8 [standard deviation]) underwent CAC CT with the use of a quantitative CT calibration phantom for evaluation of subclinical atherosclerosis. Two hundred eighty subjects also underwent CT of the chest, abdomen, and pelvis (C7 through L5). Mean BMD of three consecutive thoracic vertebrae (in the T7-T10 range) was measured in all 4126 subjects. Individual calibration factors for each phantom insert and a general calibration factor for the spine were determined for each CT scanner model. The study population was then divided into three subgroups: All calibration factors were generated from group 1 ($n = 1536$) and were applied and tested in group 2 ($n = 1587$), and effects of various image acquisition parameters were assessed in group 3 ($n = 1003$). Accuracy (bias) and precision of thoracic phantomless BMD measurements across 14 CT scanner models from five manufacturers were determined.

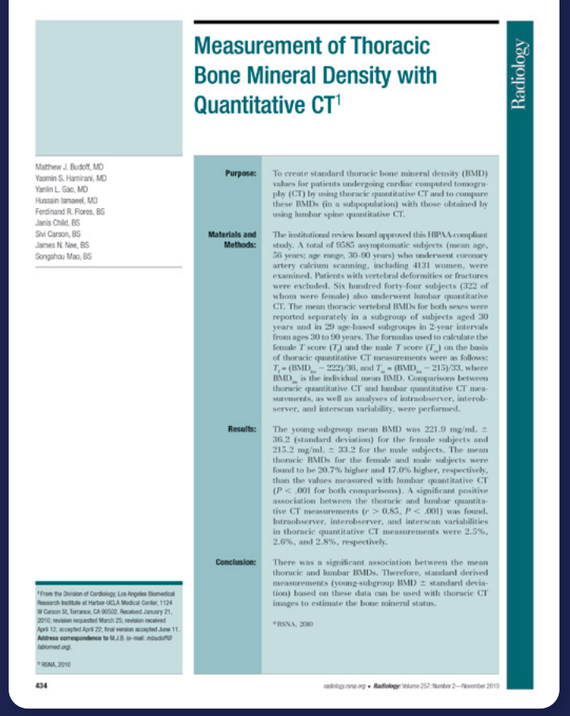
Results: Phantomless BMD values correlated highly with standard phantom-based quantitative CT BMD values ($r = 0.987$, $P < .001$). Bias was 3.9% ± 1.4 for phantomless BMD measurements, and the mean coefficient of variation for the general calibration factor was 4.9% ± 2.4.

Conclusion: Phantomless BMD can be measured accurately on CAC CT scans acquired with a variety of CT scanners without additional radiation exposure.

©RSNA, 2013

From the Los Angeles Biomedical Research Institute, Harbor-UCLA Medical Center, 1124 W Carson St, Torrance, CA 90502-2006. Received September 18, 2012; revision requested October 25; final revision received November 5; accepted November 12; final version accepted December 6. **Address correspondence to** M.J.B. (e-mail: *mbudoff@labiomed.org*).

- Budoff MJ, Malpeso JM, Zeb I, Gao YL, Li D, Choi TY, Dailing CA, Mao SS. Measurement of phantomless thoracic bone mineral density on coronary artery calcium CT scans acquired with various CT scanner models. Radiology. 2013 Jun;267(3):830-6.



Measurement of Thoracic Bone Mineral Density with Quantitative CT[1]

Radiology

Matthew J. Budoff, MD
Yasmin S. Hamirani, MD
Yanlin L. Gao, MD
Hussain Ismaeel, MD
Ferdinand R. Flores, BS
Janis Child, BS
Sivi Carson, BS
James N. Nee, BS
Songshou Mao, BS

Purpose: To create standard thoracic bone mineral density (BMD) values for patients undergoing cardiac computed tomography (CT) by using thoracic quantitative CT and to compare these BMDs (in a subpopulation) with those obtained by using lumbar spine quantitative CT.

Materials and Methods: The institutional review board approved this HIPAA-compliant study. A total of 9585 asymptomatic subjects (mean age, 56 years; age range, 30–90 years) who underwent coronary artery calcium scanning, including 4131 women, were examined. Patients with vertebral deformities or fractures were excluded. Six hundred forty-four subjects (322 of whom were female) also underwent lumbar quantitative CT. The mean thoracic vertebral BMDs for both sexes were reported separately in a subgroup of subjects aged 30 years and in 29 age-based subgroups in 2-year intervals from ages 30 to 90 years. The formulas used to calculate the female T score (T_f) and the male T score (T_m) on the basis of thoracic quantitative CT measurements were as follows: $T_f = (\text{BMD}_{ts} - 222)/36$, and $T_m = (\text{BMD}_{ts} - 213)/33$, where BMD_{ts} is the individual mean BMD. Comparisons between thoracic quantitative CT and lumbar quantitative CT measurements, as well as analyses of intraobserver, interobserver, and interscan variability, were performed.

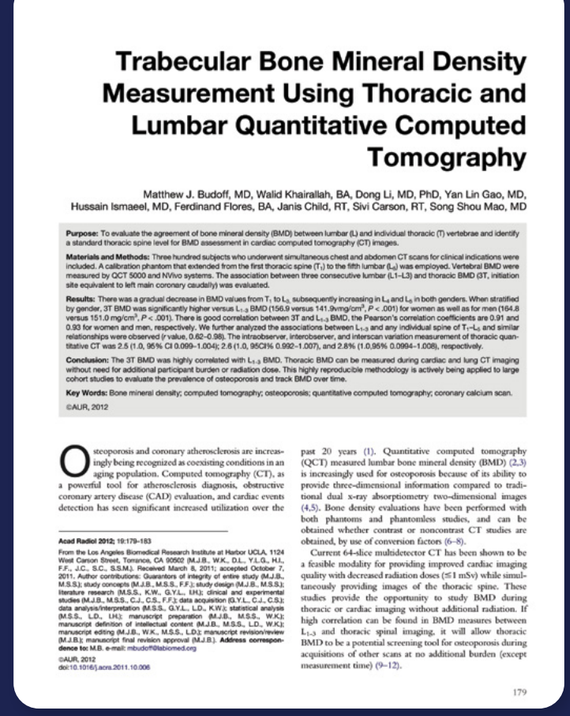
Results: The young-subgroup mean BMD was 221.9 mg/mL ± 36.2 (standard deviation) for the female subjects and 215.2 mg/mL ± 33.2 for the male subjects. The mean thoracic BMDs for the female and male subjects were found to be 20.7% higher and 17.0% higher, respectively, than the values measured with lumbar quantitative CT ($P < .001$ for both comparisons). A significant positive association between the thoracic and lumbar quantitative CT measurements ($r > 0.85$, $P < .001$) was found. Intraobserver, interobserver, and interscan variabilities in thoracic quantitative CT measurements were 2.5%, 2.6%, and 2.8%, respectively.

Conclusion: There was a significant association between the mean thoracic and lumbar BMDs. Therefore, standard derived measurements (young-subgroup BMD ± standard deviation) based on these data can be used with thoracic CT images to estimate the bone mineral status.

©RSNA, 2010

From the Division of Cardiology, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, 1124 W Carson St, Torrance, CA 90502. Received January 21, 2010; revision requested March 25; revision received April 12; accepted April 22; final version accepted June 11. **Address correspondence to** M.J.B. (e-mail: *mbudoff@labiomed.org*).

- Budoff MJ, Hamirani YS, Gao YL, Ismaeel H, Flores FR, Child J, Carson S, Nee JN, Mao S. Measurement of thoracic bone mineral density with quantitative CT. Radiology. 2010 Nov;257(2):434-40.



Trabecular Bone Mineral Density Measurement Using Thoracic and Lumbar Quantitative Computed Tomography

Matthew J. Budoff, MD, Walid Khairallah, BA, Dong Li, MD, PhD, Yan Lin Gao, MD, Hussain Ismaeel, MD, Ferdinand Flores, BA, Janis Child, RT, Sivi Carson, RT, Song Shou Mao, MD

Purpose: To evaluate the agreement of bone mineral density (BMD) between lumbar (L) and individual thoracic (T) vertebrae and identify a standard thoracic spine level for BMD assessment in cardiac computed tomography (CT) images.

Materials and Methods: Three hundred subjects who underwent simultaneous chest and abdomen CT scans for clinical indications were included. A calibration phantom that extended from the first thoracic spine (T_1) to the fifth lumbar (L_5) was employed. Vertebral BMD were measured by QCT 5000 and NVivo systems. The association between three consecutive lumbar (L1–L3) and thoracic BMD (3T, initiation site equivalent to left main coronary caudally) was evaluated.

Results: There was a gradual decrease in BMD values from T_1 to L_5, subsequently increasing in L_4 and L_5 in both genders. When stratified by gender, 3T BMD was significantly higher versus L_{1-3} BMD (156.9 versus 141.9vmg/cm^3, $P < .001$) for women as well as for men (164.8 versus 151.0 mg/cm^3, $P < .001$). There is good correlation between 3T and L_{1-3} BMD, the Pearson's correlation coefficients are 0.91 and 0.93 for women and men, respectively. We further analyzed the associations between L_{1-3} and any individual spine of T_1–L_5 and similar relationships were observed (*r* value, 0.62–0.98). The intraobserver, interobserver, and interscan variation measurement of thoracic quantitative CT was 2.5 (1.0, 95% CI 0.099–1.004); 2.6 (1.0, 95CI% 0.992–1.007), and 2.8% (1.0,95% 0.0994–1.008), respectively.

Conclusion: The 3T BMD was highly correlated with L_{1-3} BMD. Thoracic BMD can be measured during cardiac and lung CT imaging without need for additional participant burden or radiation dose. This highly reproducible methodology is actively being applied to large cohort studies to evaluate the prevalence of osteoporosis and track BMD over time.

Key Words: Bone mineral density; computed tomography; osteoporosis; quantitative computed tomography; coronary calcium scan.

Osteoporosis and coronary atherosclerosis are increasingly being recognized as coexisting conditions in an aging population. Computed tomography (CT), as a powerful tool for atherosclerosis diagnosis, obstructive coronary artery disease (CAD) evaluation, and cardiac events detection has seen significant increased utilization over the past 20 years (1). Quantitative computed tomography (QCT) measured lumbar bone mineral density (BMD) (2,3) is increasingly used for osteoporosis because of its ability to provide three-dimensional information compared to traditional dual x-ray absorptiometry two-dimensional images (4,5). Bone density evaluations have been performed with both phantoms and phantomless studies, and can be obtained whether contrast or noncontrast CT studies are obtained, by use of conversion factors (6–8).

Current 64-slice multidetector CT has been shown to be a feasible modality for providing improved cardiac imaging quality with decreased radiation doses (≤1 mSv) while simultaneously providing images of the thoracic spine. These studies provide the opportunity to study BMD during thoracic or cardiac imaging without additional radiation. If high correlation can be found in BMD measures between L_{1-3} and thoracic spinal imaging, it will allow thoracic BMD to be a potential screening tool for osteoporosis during acquisitions of other scans at no additional burden (except measurement time) (9–12).

Acad Radiol 2012; 19:179–183

From the Los Angeles Biomedical Research Institute at Harbor UCLA, 1124 West Carson Street, Torrance, CA 90502 (M.J.B., W.K., D.L., Y.L.G., H.I., F.F., J.C., S.C., S.S.M.). Received March 8, 2011; accepted October 7, 2011. Author contributions: Guarantors of integrity of entire study (M.J.B., M.S.S.); study concepts (M.J.B., M.S.S., F.F.); study design (M.J.B., M.S.S.); literature research (M.S.S., K.W., G.Y.L., I.H.); clinical and experimental studies (M.J.B., M.S.S., C.J., C.S., F.F.); data acquisition (G.Y.L., C.J., C.S.); data analysis/interpretation (M.S.S., G.Y.L., L.D., K.W.); statistical analysis (M.S.S., L.D., I.H.); manuscript preparation (M.J.B., M.S.S., W.K.); manuscript definition of intellectual content (M.J.B., M.S.S., L.D., W.K.); manuscript editing (M.J.B., W.K., M.S.S., L.D.); manuscript revision/review (M.J.B.); manuscript final revision approval (M.J.B.). **Address correspondence to:** M.B. e-mail: mbudoff@labiomed.org

doi:10.1016/j.acra.2011.10.006

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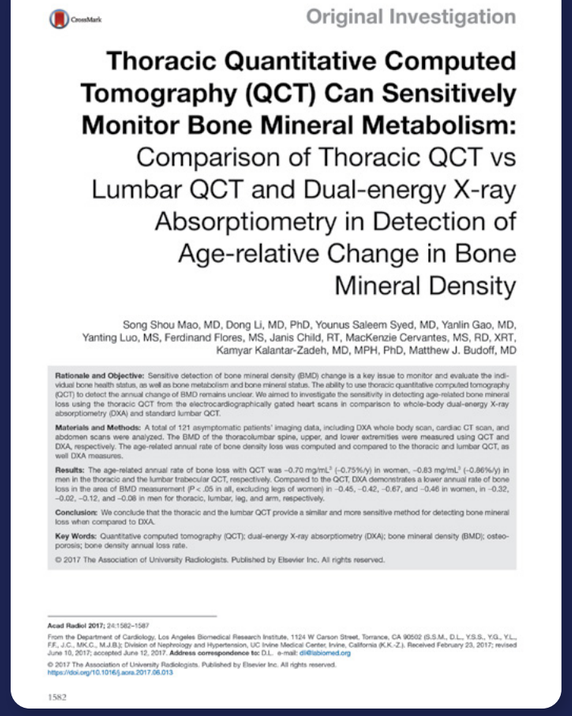

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Original Investigation

Thoracic Quantitative Computed Tomography (QCT) Can Sensitively Monitor Bone Mineral Metabolism: Comparison of Thoracic QCT vs Lumbar QCT and Dual-energy X-ray Absorptiometry in Detection of Age-relative Change in Bone Mineral Density

Song Shou Mao, MD, Dong Li, MD, PhD, Younus Saleem Syed, MD, Yanlin Gao, MD, Yanting Luo, MS, Ferdinand Flores, MS, Janis Child, RT, MacKenzie Cervantes, MS, RD, XRT, Kamyar Kalantar-Zadeh, MD, MPH, PhD, Matthew J. Budoff, MD

Rationale and Objective: Sensitive detection of bone mineral density (BMD) change is a key issue to monitor and evaluate the individual bone health status, as well as bone metabolism and bone mineral status. The ability to use thoracic quantitative computed tomography (QCT) to detect the annual change of BMD remains unclear. We aimed to investigate the sensitivity in detecting age-related bone mineral loss using the thoracic QCT from the electrocardiographically gated heart scans in comparison to whole-body dual-energy X-ray absorptiometry (DXA) and standard lumbar QCT.

Materials and Methods: A total of 121 asymptomatic patients' imaging data, including DXA whole body scan, cardiac CT scan, and abdomen scans were analyzed. The BMD of the thoracolumbar spine, upper, and lower extremities were measured using QCT and DXA, respectively. The age-related annual rate of bone density loss was computed and compared to the thoracic and lumbar QCT, as well DXA measures.

Results: The age-related annual rate of bone loss with QCT was −0.70 mg/mL^2 (-0.75%/y) in women, −0.83 mg/mL^2 (-0.86%/y) in men in the thoracic and the lumbar trabecular QCT, respectively. Compared to the QCT, DXA demonstrates a lower annual rate of bone loss in the area of BMD measurement ($P < .05$ in all, excluding legs of women) in −0.45, −0.42, −0.67, and −0.46 in women, in −0.32, −0.02, −0.12, and −0.08 in men for thoracic, lumbar, leg, and arm, respectively.

Conclusion: We conclude that the thoracic and the lumbar QCT provide a similar and more sensitive method for detecting bone mineral loss when compared to DXA.

Key Words: Quantitative computed tomography (QCT); dual-energy X-ray absorptiometry (DXA); bone mineral density (BMD); osteoporosis; bone density annual loss rate.

Acad Radiol 2017; 24:1582–1587

From the Department of Cardiology, Los Angeles Biomedical Research Institute, 1124 W Carson Street, Torrance, CA 90502 (S.S.M., D.L., Y.S.S., Y.G., Y.L., F.F., J.C., MK.C., M.J.B.); Division of Nephrology and Hypertension, UC Irvine Medical Center, Irvine, California (K.K.-Z.). Received February 23, 2017; revised June 10, 2017; accepted June 12, 2017. **Address correspondence to:** D.L. e-mail: dli@labiomed.org

https://doi.org/10.1016/j.acra.2017.06.013

- Song Shou Mao, Dong Li, Younus Saleem Syed, Yanlin Gao, Yanting Luo, Ferdinand Flores, Janis Child, MacKenzie Cervantes, Kamyar Kalantar-Zadeh, Matthew J. Budoff, Thoracic Quantitative Computed Tomography (QCT) Can Sensitively Monitor Bone Mineral Metabolism: Comparison of Thoracic QCT vs Lumbar QCT and Dual-energy X-ray Absorptiometry in Detection of Age-relative Change in Bone Mineral Density, Academic Radiology, Volume 24, Issue 12, 2017, Pages 1582-1587, ISSN 1076-6332.

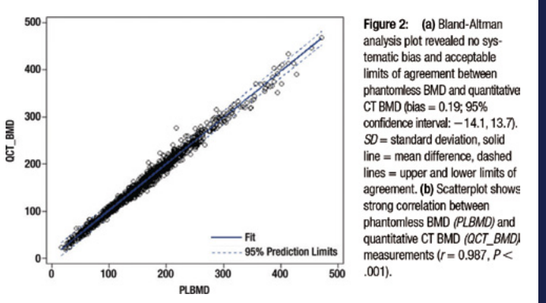
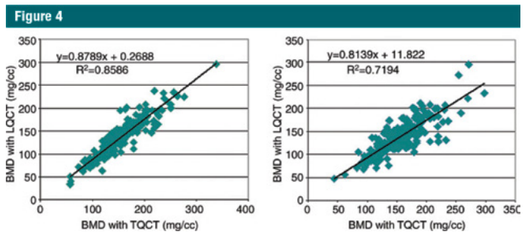
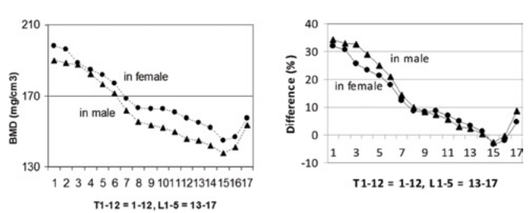


Figure 2: **(a)** Bland-Altman analysis plot revealed no systematic bias and acceptable limits of agreement between phantomless BMD and quantitative CT BMD (bias = 0.19; 95% confidence interval: −14.1, 13.7). *SD* = standard deviation, solid line = mean difference, dashed lines = upper and lower limits of agreement. **(b)** Scatterplot shows strong correlation between phantomless BMD *(PLBMD)* and quantitative CT BMD *(QCT_BMD)* measurements ($r = 0.987$, $P <$ .001).

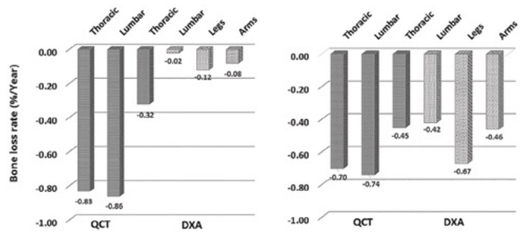
- A significant positive correlation was found between phantomless and quantitative CT BMD measurements (r = 0.98, P , .001)



- Linear graphs illustrate comparison of lumbar (y) and thoracic (x) quantitative CT measurements. BMDs measured with lumbar and thoracic quantitative CT were highly correlated. BMDs were systematically higher with thoracic CT in (a) 322 male and (b) 322 female subjects.



- Bone mineral density (BMD) value of 17 vertebrae by the QCT technique.
- The percent difference between L1–3 and 17 individual measurements.

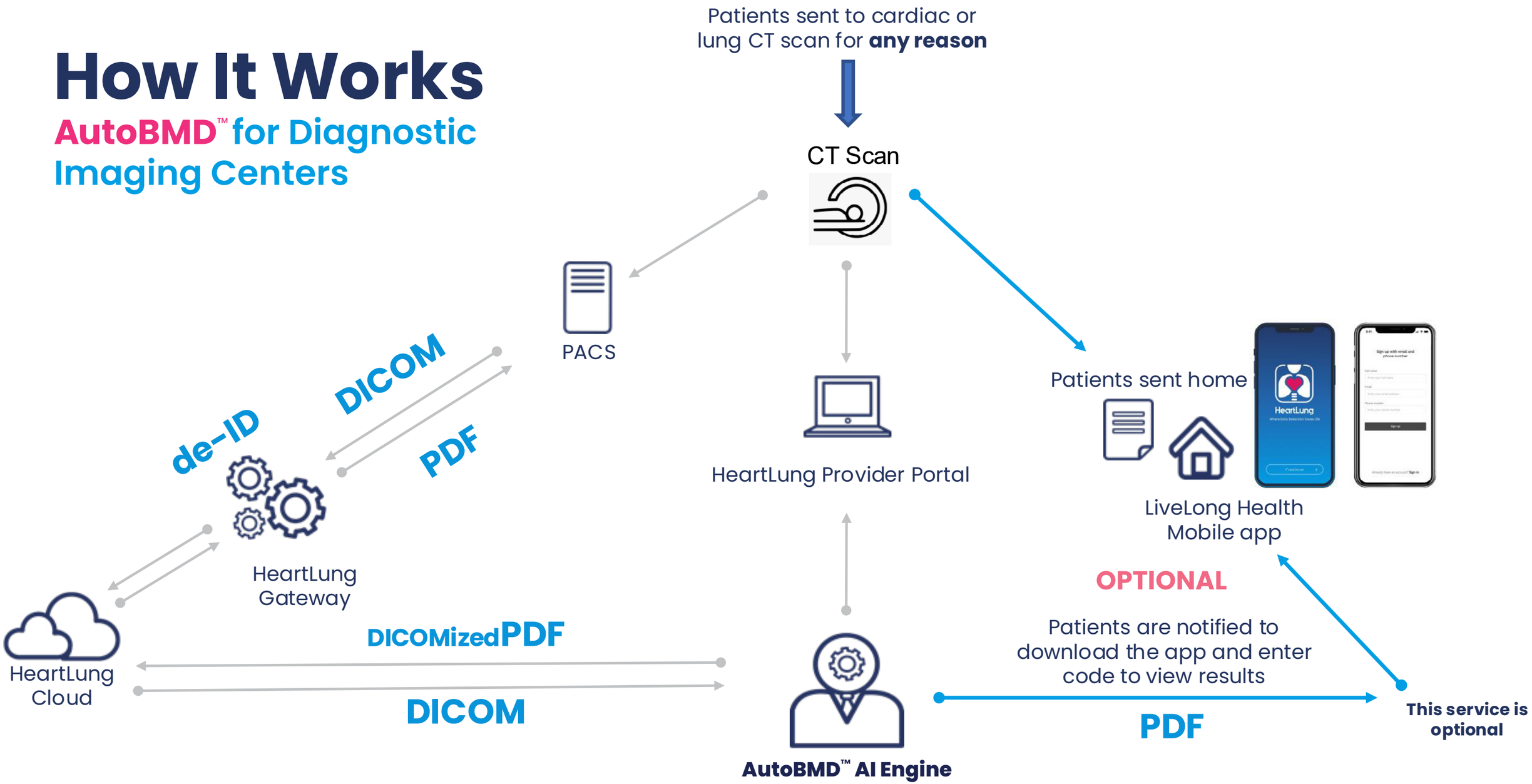


- Comparison of QCT and DXA in the age-related annual loss rate of bone in women (left panel) and men (right panel). DXA, dualenergy X-ray absorptiometry; QCT, quantitative computed tomography.

Simple & Easy Workflow Integration

How It Works

AutoBMD™ for Diagnostic Imaging Centers



AutoBMD™ AI

HeartLung.AI

Provider Q&A

- **Is AutoBMD™ reimbursed? If yes, what CPT code?**

  Yes, AutoBMD™ AI is reimbursed by Medicare and private payers as part of osteoporosis screening mandate by US Preventative Task Force Services (CPT 77078). AutoBMD™ report is based on qCT (Quantitative CT) and uses a 3D bone density analysis that is superior to DEXA which is 2D. The only advantage of DEXA over qCT is lower radiation exposure, however in the case of AutoBMD™, the radiation is ZERO because it is an opportunistic screening as an add-on to CT scans ordered for other reasons.

- **How does my PACS connect to AutoBMD™ AI cloud?**

  Your PACS can easily connect to AutoBMD™ cloud through a direct link using your unique AE title generated by HeartLung; or via a HeartLung Gateway installed and no hardware installation is required. The scanned CT image is sent from your PACS to AutoBMD™ AI cloud where the report is created and sent back to you and is also viewable on HeartLung's Provider & Patient Portal. **https://provider.heartlung.ai**

- **Do I need a physician's order to add an AutoBMD™ AI report to a thoracic or abdominal CT scan?**

  Opportunistic osteoporosis screening may not require a physician order for reimbursement purposes. However, this may vary by the payer and the state law. Depending on the state certain restrictions may apply to self-referring screening. Because AutoBMD™ poses no radiation risk or procedural issues, this may be lesser of an issue in those states. Nonetheless, because referring phycisians are responsible for treating patients with osteoporosis, we strongly recommend informing and engaging all referring phycisians.

AutoBMD™ AI

HeartLung.AI

Provider Q&A

- **Can AutoBMD™ be done on patients who have done DEXA in the past?**

  Yes, it can but for reimbursement purposes certain restriction may apply. If DEXA was less than 2 years ago, chances are the payers may not cover an additional bone density report. As stated previously, because there is no additional radiation to patient, informing them of their options is recommended.

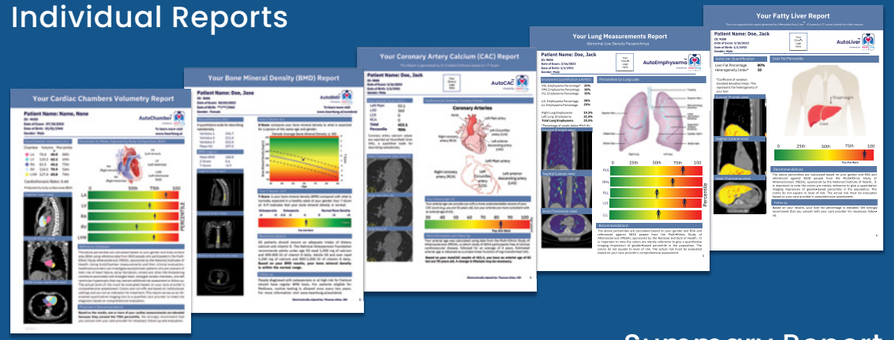
- **Which image series should I send to AutoBMD™ AI Cloud?**

  Only send one axial series to AutoBMD™ AI cloud. For example, the axial series used for coronary artery calcium scoring or lung cancer screening would work. The AutoBMD™ AI module works based on intensity (Hounsfield Units), so please send images generated using the standard convolution kernel without any modifications or reconstructions.

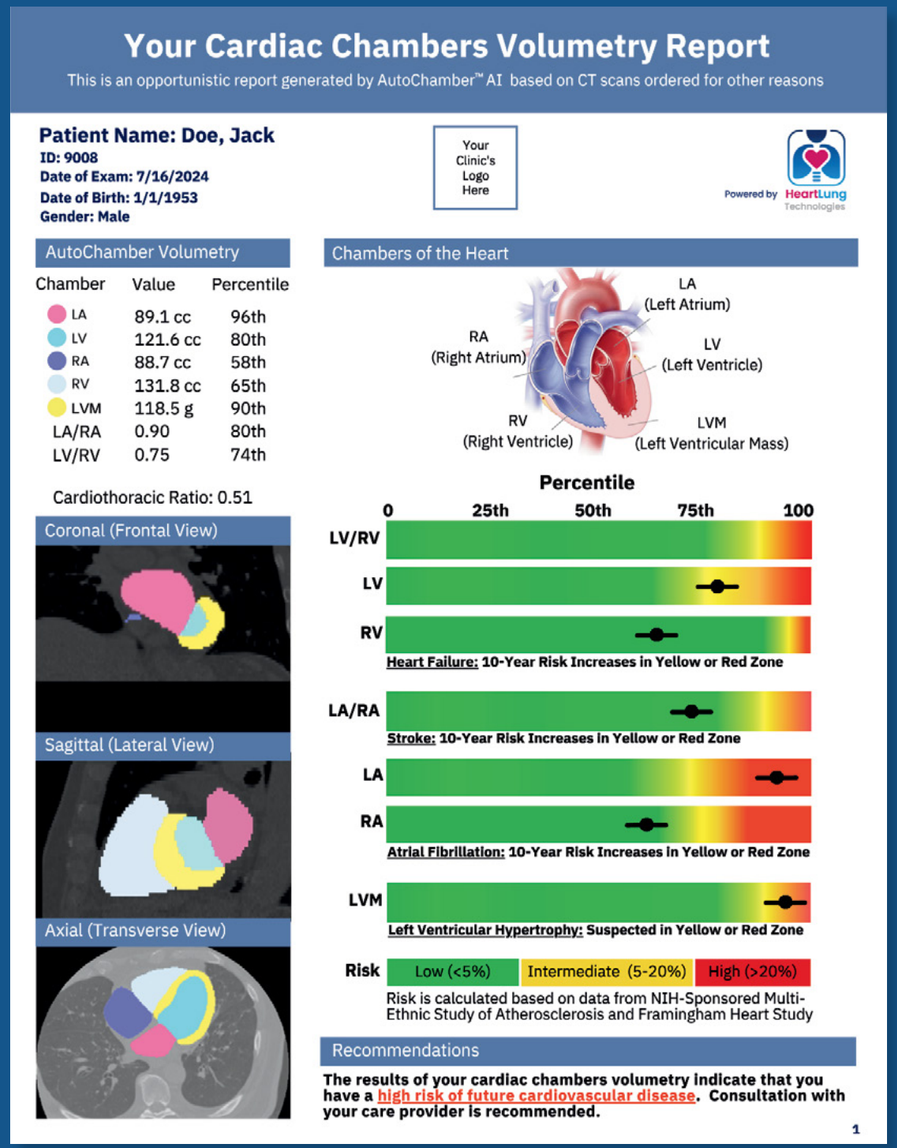
- **How do I start a free trial?**

  Simply create an account at **https://provider.heartlung.ai** and send your first set of DICOM images using the unique AE title that our system generates for your center. You will be contacted within 24 hours for verification and testing the setup. Reports are sent back to PACS in less than 5 minutes as a DICOMized PDF, helping providers detect osteoporosis or osteopenia before the patient even leaves the office. The trial includes 10 free cases, and reports are Medicare-reimbursable. No hardware required. No IT complexity. Just turn on the AutoBMD™ pipeline and start identifying at-risk patients using scans you're already doing.

Individual Reports



Summary Report



Your Cardiac Chambers Volumetry Report

This is an opportunistic report generated by AutoChamber™ AI based on CT scans ordered for other reasons

Patient Name: Doe, Jack
ID: 9008
Date of Exam: 7/16/2024
Date of Birth: 1/1/1953
Gender: Male

Your Clinic's Logo Here

Powered by HeartLung Technologies

AutoChamber Volumetry

Chamber	Value	Percentile
LA	89.1 cc	96th
LV	121.6 cc	80th
RA	88.7 cc	58th
RV	131.8 cc	65th
LVM	118.5 g	90th
LA/RA	0.90	80th
LV/RV	0.75	74th

Cardiothoracic Ratio: 0.51

Coronal (Frontal View)

Sagittal (Lateral View)

Axial (Transverse View)

Chambers of the Heart

LA (Left Atrium)
RA (Right Atrium)
LV (Left Ventricle)
RV (Right Ventricle)
LVM (Left Ventricular Mass)

Percentile

0 25th 50th 75th 100

LV/RV
LV
RV

Heart Failure: 10-Year Risk Increases in Yellow or Red Zone

LA/RA

Stroke: 10-Year Risk Increases in Yellow or Red Zone

LA
RA

Atrial Fibrillation: 10-Year Risk Increases in Yellow or Red Zone

LVM

Left Ventricular Hypertrophy: Suspected in Yellow or Red Zone

Risk Low (<5%) | Intermediate (5-20%) | High (>20%)

Risk is calculated based on data from NIH-Sponsored Multi-Ethnic Study of Atherosclerosis and Framingham Heart Study

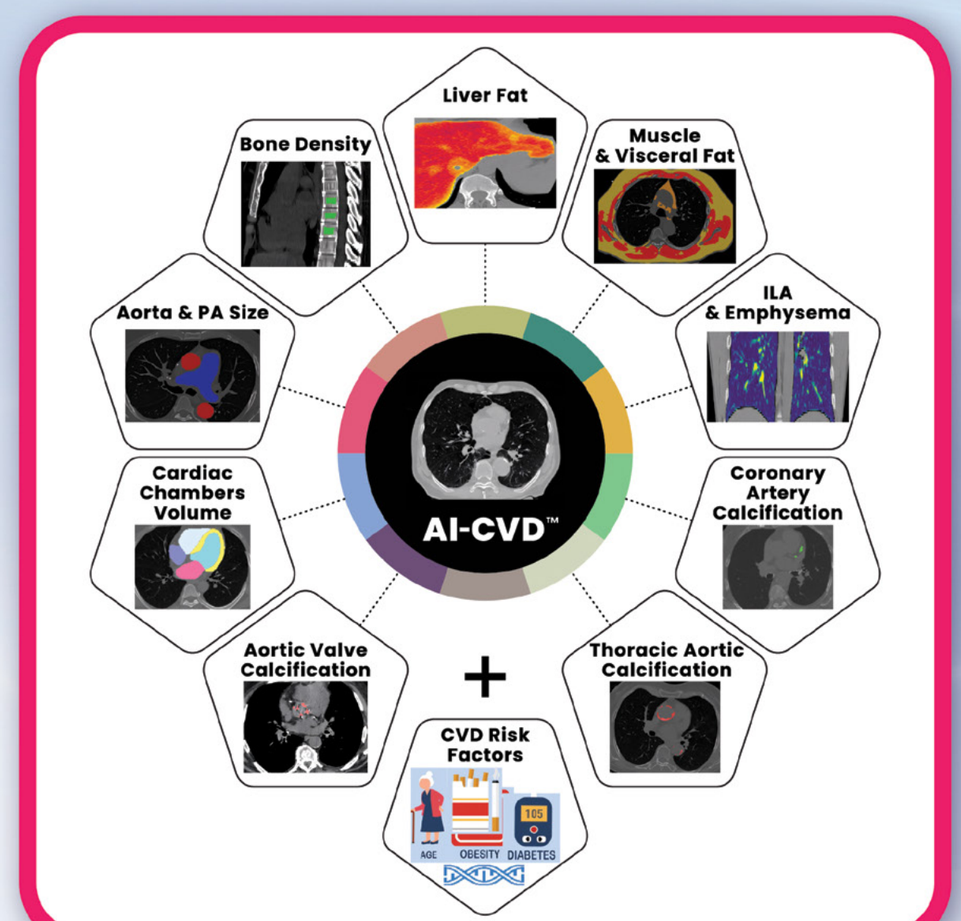
Recommendations

The results of your cardiac chambers volumetry indicate that you have a high risk of future cardiovascular disease. Consultation with your care provider is recommended.

1

AI-CVD™

CT-BASED AI SOLUTIONS ENABLING EARLY DETECTION AND PREVENTION OF CARDIOVASCULAR DISEASE



To learn more about **AI-CVD™**, which includes **AutoBMD™** Reports, scan the QR code or visit: **https://heartlung.ai/aicvd**

Your Bone Mineral Density (BMD) Report

Patient Name: Doe, Jane
ID: 9008
Date of Exam: 2/16/2023
Date of Birth: 1/1/1953
Gender: Female

Your Clinic's Logo Here

AutoBMD™ Powered by HeartLung Technologies

To learn more visit www.AutoBMD.ai

Hounsfield Unit (HU)

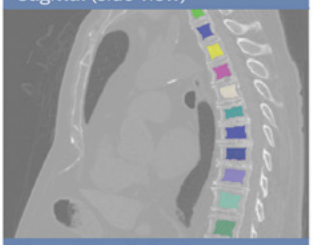
A quantitive scale for describing radiodensity.

Vertebra1	114.6
Vertebra2	100.1
Vertebra3	102.7
Mean HU	105.8

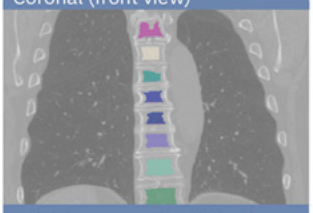
BMD (mg/cc)

Mean BMD	106
Z-score	-2
T-score	-3.2

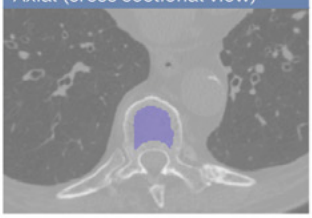
Sagittal (side view)



Coronal (front view)

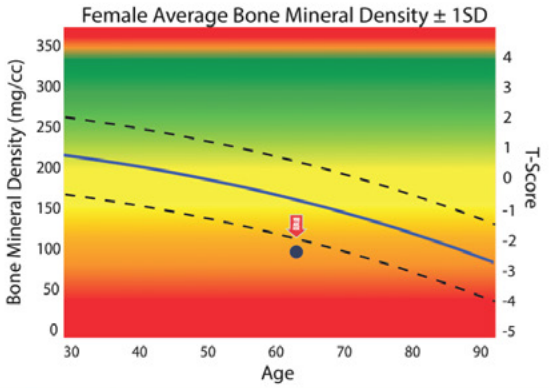


Axial (cross sectional view)



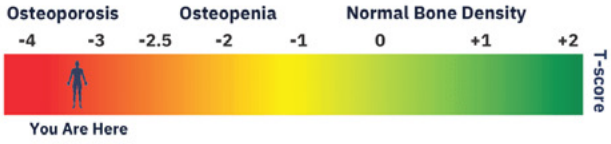
Your Z-score: -2.0

Z-score compares your bone density to average values for a person of your same age and gender.



Your T-score: -3.2

T-score is your bone density compared with what is normally expected in a healthy adult of your sex. *Your T-Score of -3.2 indicates you likely have osteoporosis (severe bone loss).*



Recommendations

All patients should ensure an adequate intake of dietary calcium and vitamin D. The National Osteopororis Foundation recommends adults under age 50 need 1,000 mg of calcium and 400-800 IU of vitamin D daily. Adults 50 and over need 1,200 mg of calcium and 800-1,000 IU of vitamin D daily. **Based on your BMD results, you have osteoporosis and should seek follow up care with your physician.**

Follow up

People with diagnosed cases of osteoporosis or at high risk for fracture should have regular BMD tests. For patients eligible for Medicare, routine testing is allowed once every 2 years. For more information visit www.AutoBMD.ai.

Electronically signed by: Thomas Atlas, MD 1

HeartLung Technologies Co.
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Houston, TX 77021
(310) 510-6004
www.HeartLung.ai
contact@heartlung.ai

HeartLung's AutoBMD™ is the first and only FDA-approved AI-enabled bone densitometry with "opportunistic screening" indication that is DEXA-equivalent and works both on thoracic and abdominal & pelvic CT scans.

HeartLung Technologies

FDA BREAKTHROUGH DEVICE DESIGNATION

Introducing AutoChamber™ AI

AutoChamber™ is the first FDA-approved AI that received "**Breakthrough**" designation for enabling physicians to detect patients with enlarged cardiac chambers and left ventricular hypertrophy that are invisible to the human eye.

Effective April 1, 2025, Medicare approved reimbusement for AutoChamber™ under HCPCS G0183.

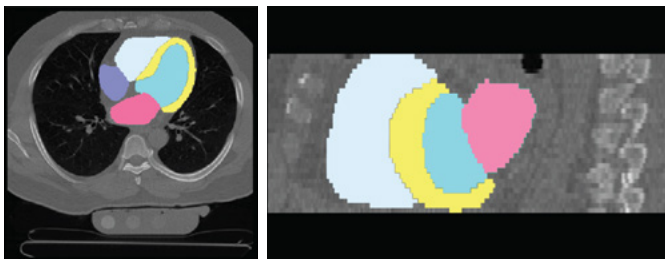
Every year over 10 million chest CT scans are done in the US alone and among them many asymptomatic patients with enlarged heart chambers are missed resulting in late-stage heart failure, atrial fibrillation, stroke, and sudden cardiac death. AutoChamber™ AI can help physicians fill this gap and save many lives from preventable cardiovascular death.

Case Example 1

Developed HF in 11 years

Male, Age: 54
CAC Score: 0
10-year ASCVD Risk: 4.1%

LV Volume: 198.4 cc (99th percentile)
Cohort LV Volume: 116.9 ± 24.9 cc

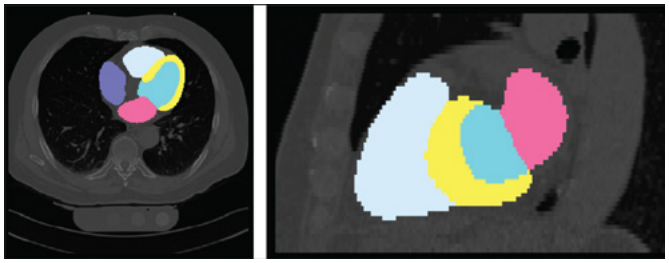


Case Example 2

Developed AF/stroke in 9 years

Female, Age: 57
CAC Score: 0
10-year ASCVD Risk: 1.4%

LA Volume: 84.6 cc (96th percentile)
Cohort LA Volume: 55.8 ± 14.1 cc



LA LV RA RV LV Mass

These lives could have been saved by AutoChamber™

These two case examples show patients who were deemed low risk because of a Coronary Artery Calcium (CAC) score of 0. Both patients later developed fatal stroke, atrial fibrillation (AF), and heart failure (HF).

AutoChamber™ was run on these patients' scans and found that both cases had enlarged cardiac chambers and were at high risk of heart failure, atrial fibrilation, and stroke. The add-on AutoChamber™ report could have been life-saving.

AutoChamber™ AI provides highly significant added values to CAC scans, CCTA, CPTA, LDCT, and chest diagnostic CT scans.

SAMPLE REPORT

Your Cardiac Chambers Volumetry Report

This is an opportunistic report generated by AutoChamber™ AI based on CT scans ordered for other reasons

Patient Name: Doe, Jack
ID: 9008
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Date of Birth: 1/1/1953
Gender: Male

Clinic Logo

Powered by HeartLung Technologies

AutoChamber Volumetry

Chamber	Value	Percentile
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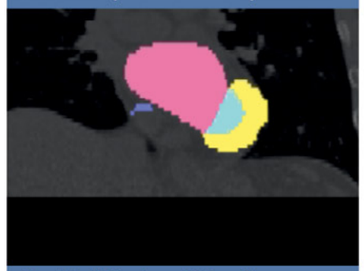
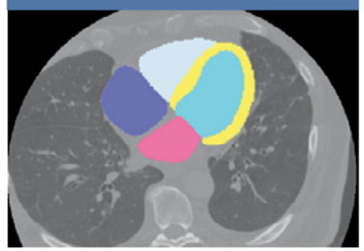
Cardiothoracic Ratio: 0.51

Coronal (Frontal View)

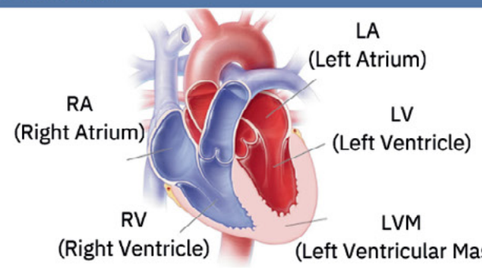


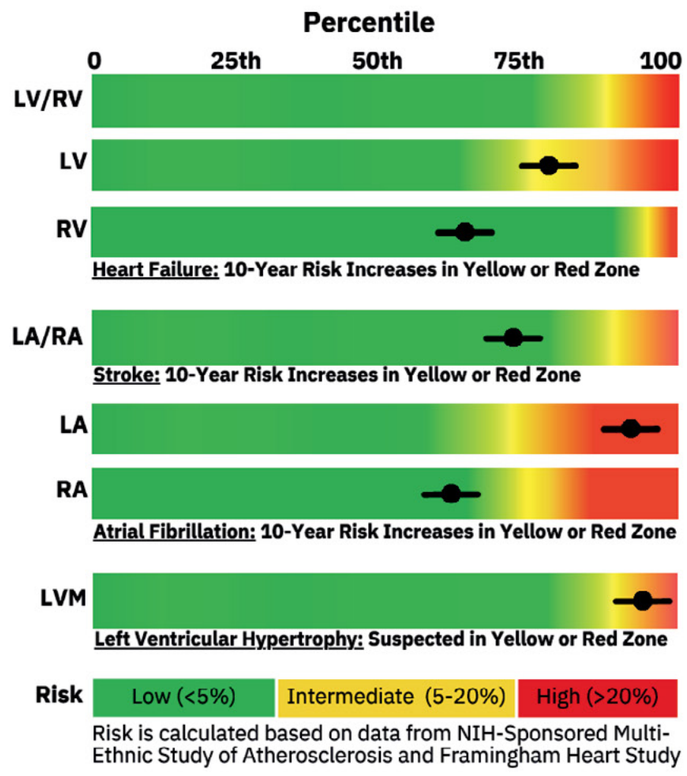
Sagittal (Lateral View)

Axial (Transverse View)



Chambers of the Heart





Risk is calculated based on data from NIH-Sponsored Multi-Ethnic Study of Atherosclerosis and Framingham Heart Study

Recommendations

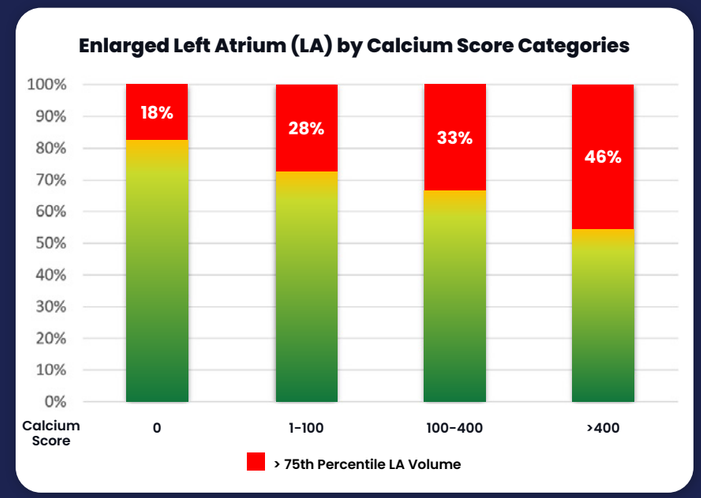
The results of your cardiac chambers volumetry indicate that you have a high risk of future cardiovascular disease. Consultation with your care provider is recommended.

Detect Hidden Heart Disease

Catch What A Calcium Score Can't!

This graph shows a significant percentage of people who are classified as low risk based on coronary artery calcium (CAC) scores of zero or below 100 have an enlarged left atrium (LA) that puts them at a high risk of atrial fibrillation (AF) and stroke.

Similar results were found for enlarged left ventricle (LV) putting patients at a high risk of heart failure (HF).



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- Naghavi M, Reeves A, Budoff M, Li D, Atlas K, Zhang C, Atlas T, Roy SK, Henschke CI, Wong ND, Defilippi C, Levy D, Yankelevitz DF. AI-enabled cardiac chambers volumetry in coronary artery calcium scans (AI-CACTM) predicts heart failure and outperforms NT-proBNP: The multi-ethnic study of Atherosclerosis. J Cardiovasc Comput Tomogr. 2024 Jul-Aug;18(4):392-400.
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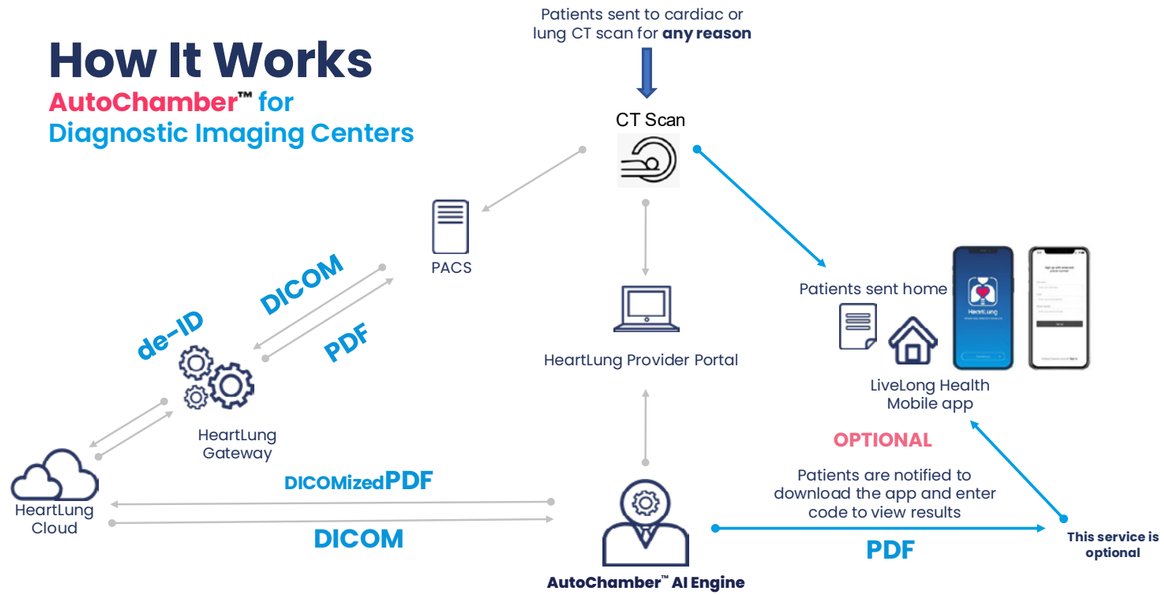
- Naghavi M, Reeves, A.P., Atlas, K., Zhang C, Atlas T, Henschke C, Yankelevitz D, Budoff M, Li D, Roy S, Nasir K, Molloi S, Fayad Z, McConnell M, Kakadiaris L, Maron D, Narula J, Williams K, Shah P, Levy D, Wong N. Artificial intelligence applied to coronary artery calcium scans (AI-CAC) significantly improves cardiovascular events prediction. npj Digit. Med. 7, 309 (2024).

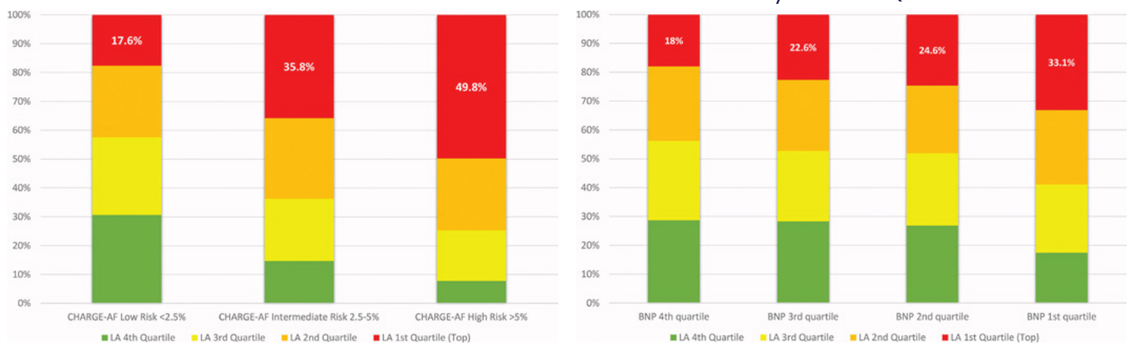
Simple & Easy Workflow Integration

How It Works

AutoChamber™ for Diagnostic Imaging Centers



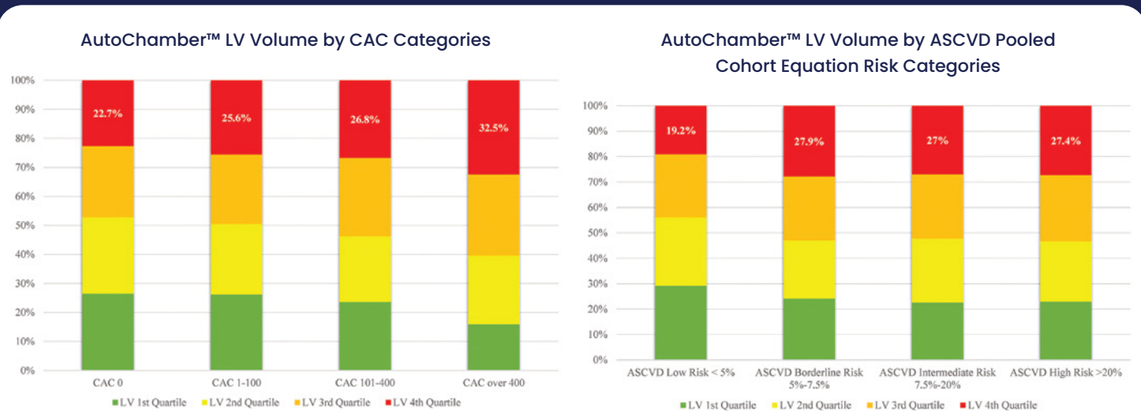
AutoChamber™



- Distribution of AI-CAC LA Volume by CAC Categories, NT-proBNP Quartiles, and CHARGE-AF Risk Score Quartiles.
  (A) Quartiles of AI-CAC LA volume by 5-year CHARGE-AF risk categories. (B) Quartiles of AI-CAC LA volume by NT-proBNP quartiles.

Take Home Point

AutoChamber™ detects a significant portion of high-risk patients who are wrongly classified as low-risk by existing standards such as CHARGE-AF, BNP, CAC score and ASCVD score.



- Quartiles of AI-CAC Left Ventricle (LV) Volume by coronary artery calcium (CAC) and ASCVD Pooled Cohorts Equation Categories.

Scientific Publications

HeartLung.AI

Journal of Cardiovascular Computed Tomography 18 (2024) 392–400

Contents lists available at ScienceDirect

Journal of Cardiovascular Computed Tomography

journal homepage: www.JournalofCardiovascularCT.com

Research paper

AI-enabled cardiac chambers volumetry in coronary artery calcium scans (AI-CAC™) predicts heart failure and outperforms NT-proBNP: The multi-ethnic study of Atherosclerosis

Morteza Naghavi [a,*], Anthony Reeves [b], Matthew Budoff [c], Dong Li [c], Kyle Atlas [a], Chenyu Zhang [a], Thomas Atlas [d], Sion K. Roy [e], Claudia I. Henschke [e], Nathan D. Wong [f], Christopher Defilippi [g], Daniel Levy [h], David F. Yankelevitz [e]

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ARTICLE INFO

Keywords:
Left ventricular volume
Coronary artery calcium
Artificial intelligence
Heart failure
NT-proBNP

ABSTRACT

Introduction: Coronary artery calcium (CAC) scans contain useful information beyond the Agatston CAC score that is not currently reported. We recently reported that artificial intelligence (AI)-enabled cardiac chambers volumetry in CAC scans (AI-CAC™) predicted incident atrial fibrillation in the Multi-Ethnic Study of Atherosclerosis (MESA). In this study, we investigated the performance of AI-CAC cardiac chambers for prediction of incident heart failure (HF).

Methods: We applied AI-CAC to 5750 CAC scans of asymptomatic individuals (52% female, White 40%, Black 26%, Hispanic 22% Chinese 12%) free of known cardiovascular disease at the MESA baseline examination (2000–2002). We used the 15-year outcomes data and compared the time-dependent area under the curve (AUC) of AI-CAC volumetry versus NT-proBNP, Agatston score, and 9 known clinical risk factors (age, gender, diabetes, current smoking, hypertension medication, systolic and diastolic blood pressure, LDL, HDL for predicting incident HF over 15 years.

Results: Over 15 years of follow-up, 256 HF events accrued. The time-dependent AUC (95% CI) at 15 years for predicting HF with AI-CAC all chambers volumetry (0.86 [0.82,0.91]) was significantly higher than NT-proBNP (0.74 [0.69, 0.77]) and Agatston score (0.71 [0.68, 0.78]) ($p < 0.0001$), and comparable to clinical risk factors (0.85, $p = 0.4141$). Category-free Net Reclassification Index (NRI) (95% CI) adding AI-CAC LV significantly improved on clinical risk factors (0.32 [0.16,0.41]), NT-proBNP (0.46 [0.33,0.58]), and Agatston score (0.71 [0.57,0.81]) for HF prediction at 15 years ($p < 0.0001$).

Conclusion: AI-CAC volumetry significantly outperformed NT-proBNP and the Agatston CAC score, and significantly improved the AUC and category-free NRI of clinical risk factors for incident HF prediction.

1. Introduction

Coronary artery calcium (CAC) scoring is a strong predictor of coronary heart disease (CHD) events in asymptomatic individuals.[1] However, it is a weak predictor of heart failure (HF).[2] HF is a significant healthcare burden due to large and rising numbers of HF hospitalizations and rehospitalizations.[3] Approximately 2% of the total US healthcare budget is spent on HF, and half of that is attributable to late diagnosis leading to inpatient admissions.[4] Numerous studies have highlighted the importance of early detection of asymptomatic high-risk patients to prevent progression to overt clinical HF. These high-risk patients include those with asymptomatic left ventricular dysfunction (ALVD), left ventricular

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Research paper

AI-enabled left atrial volumetry in coronary artery calcium scans (AI-CAC™) predicts atrial fibrillation as early as one year, improves CHARGE-AF, and outperforms NT-proBNP: The multi-ethnic study of atherosclerosis

Morteza Naghavi [a,*], David Yankelevitz [b], Anthony P. Reeves [c], Matthew J. Budoff [d], Dong Li [d], Kyle Atlas [a], Chenyu Zhang [a], Thomas L. Atlas [d], Seth Lirette [e], Jakob Wasserthal [f], Sion K. Roy [d], Claudia Henschke [b], Nathan D. Wong [g], Christopher Defilippi [h], Susan R. Heckbert [i], Philip Greenland [j]

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ARTICLE INFO

Keywords:
Coronary artery calcium
Atrial fibrillation
Left atrial volume
Artificial intelligence
CHARGE-AF
NT-proBNP

ABSTRACT

Background: Coronary artery calcium (CAC) scans contain actionable information beyond CAC scores that is not currently reported.

Methods: We have applied artificial intelligence-enabled automated cardiac chambers volumetry to CAC scans (AI-CAC™) to 5535 asymptomatic individuals (52.2% women, ages 45–84) that were previously obtained for CAC scoring in the baseline examination (2000–2002) of the Multi-Ethnic Study of Atherosclerosis (MESA). AI-CAC took on average 21 s per CAC scan. We used the 5-year outcomes data for incident atrial fibrillation (AF) and assessed discrimination using the time-dependent area under the curve (AUC) of AI-CAC LA volume with known predictors of AF, the CHARGE-AF Risk Score and NT-proBNP. The mean follow-up time to an AF event was 2.9 ± 1.4 years.

Results: At 1,2,3,4, and 5 years follow-up 36, 77, 123, 182, and 236 cases of AF were identified, respectively. The AUC for AI-CAC LA volume was significantly higher than CHARGE-AF for Years 1, 2, and 3 (0.83 vs. 0.74, 0.84 vs. 0.80, and 0.81 vs. 0.78, respectively, all $p < 0.05$), but similar for Years 4 and 5, and significantly higher than NT-proBNP at Years 1–5 (all $p < 0.01$), but not for combined CHARGE-AF and NT-proBNP at any year. AI-CAC LA significantly improved the continuous Net Reclassification Index for prediction of AF over years 1–5 when added to CHARGE-AF Risk Score (0.60, 0.28, 0.32, 0.19, 0.24), and NT-proBNP (0.68, 0.44, 0.42, 0.30, 0.37) (all $p < 0.01$).

Conclusion: AI-CAC LA volume enabled prediction of AF as early as one year and significantly improved on risk classification of CHARGE-AF Risk Score and NT-proBNP.

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E-mail address: mn@vp.org (M. Naghavi).

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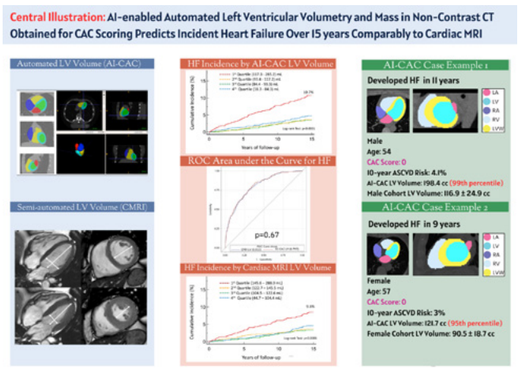
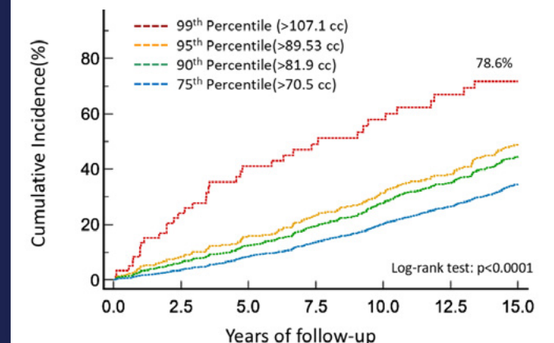


- AutoChamber AI applied opportunistically to existing CAC scans predicted future heart failure similarly to a cardiac MRI, which is much more expensive and time-consuming.



- Cumulative incidence of atrial fibrillation (AF) in the top quartile of AI-CAC left atrial (LA) volume (adjusted by BSA).

AutoChamber™

Comparing Incident Heart Failure Associated with Enlarged Cardiac Chambers versus Diabetes: An AI-CVD Study within the Multi-Ethnic Study of Atherosclerosis (MESA)

Morteza Naghavi, Seyed Reza Mirjalili, Kyle Atlas, Anthony P. Reeves, Chenyu Zhang, Jakob Wasserthal, Amir Azimi, Thomas Atlas, Claudia I. Henschke, David F. Yankelevitz, Javier J. Zulueta, Jeffrey Mechanick, Andrea Branch, Ning Ma, Rowena Yip, Wenjun Fan, Sion K. Roy, Khurram Nasir, Sabee Molloi, Zahi Fayad, Michael V. McConnell, Ioannis A. Kakadiaris, George Abela, Rozemarijn Vliegenthart, David J. Maron, Jagat Narula, Kim Williams, Prediman K. Shah, Matthew J. Budoff, Daniel Levy, Roxana Mehran, Robert A.Kloner, Nathan D. Wong.

Abstract

Background and aims:

Type 2 diabetes mellitus (T2DM) is classified as Stage A (at risk) heart failure (HF). We previously showed that artificial intelligence (AI)-detected enlarged cardiac chambers particularly left atrium (LA), left ventricle (LV) and increased LV mass in coronary artery calcium (CAC) scans were strongly associated with HF. In this study, we compare the incidence of HF in individuals with enlarged chambers vs. T2DM.

Methods:

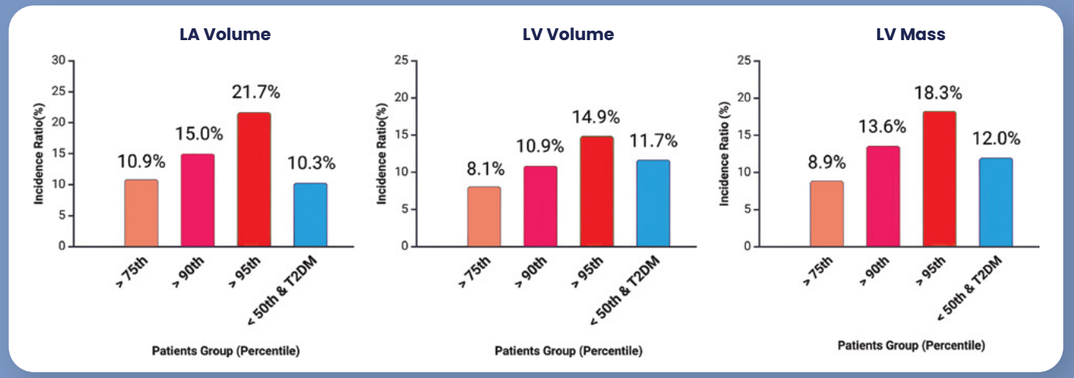
AI-enabled cardiac chambers volumetry was applied to baseline CAC-scans of 5789 MESA participants aged 45–84 (47.7% male, 12.5% T2DM). LA, LV, and LV mass percentiles were indexed by body surface area. We used Cox regression and Kaplan-Meier with log-rank tests to evaluate HF incidence over 19 years. Enlarged chambers were defined as ≥95th percentile.

Results:

In non-T2DM individuals, enlarged LA (HR:5.0 [3.4–7.4]), LV (HR:5.5 [3.7–8.3]), and LV mass (HR:5.4 [3.7–7.9]) were independently associated with HF after full adjustment. Non-T2DM individuals with enlarged LA had higher HF incidence than those with T2DM and normal LA volume (21.7% vs. 10.3%, P=0.001); similar findings were observed for LV mass (18.3% vs. 12.0%, P=0.04). Those with both T2DM and enlarged chambers had higher HF risk compared to either condition alone; except for LA where the risk was not significantly different from having an enlarged LA alone.

Conclusion:

Enlarged LA, LV, and LV mass without T2DM exhibited a greater risk of incident HF than T2DM with normal chambers. Adding cardiac chambers volume and mass to HF staging should be investigated.



Scientific Publications

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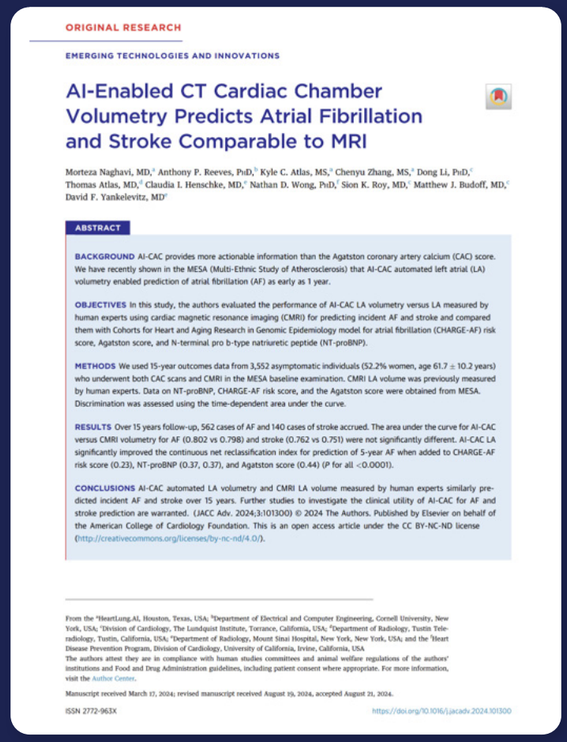

ORIGINAL RESEARCH

EMERGING TECHNOLOGIES AND INNOVATIONS

AI-Enabled CT Cardiac Chamber Volumetry Predicts Atrial Fibrillation and Stroke Comparable to MRI

Morteza Naghavi, MD,[a] Anthony P. Reeves, PhD,[b] Kyle C. Atlas, MS,[a] Chenyu Zhang, MS,[a] Dong Li, PhD,[c] Thomas Atlas, MD,[d] Claudia I. Henschke, MD,[e] Nathan D. Wong, PhD,[f] Sion K. Roy, MD,[c] Matthew J. Budoff, MD,[c] David F. Yankelevitz, MD[e]

ABSTRACT

BACKGROUND AI-CAC provides more actionable information than the Agatston coronary artery calcium (CAC) score. We have recently shown in the MESA (Multi-Ethnic Study of Atherosclerosis) that AI-CAC automated left atrial (LA) volumetry enabled prediction of atrial fibrillation (AF) as early as 1 year.

OBJECTIVES In this study, the authors evaluated the performance of AI-CAC LA volumetry versus LA measured by human experts using cardiac magnetic resonance imaging (CMRI) for predicting incident AF and stroke and compared them with Cohorts for Heart and Aging Research in Genomic Epidemiology model for atrial fibrillation (CHARGE-AF) risk score, Agatston score, and N-terminal pro b-type natriuretic peptide (NT-proBNP).

METHODS We used 15-year outcomes data from 3,552 asymptomatic individuals (52.2% women, age 61.7 ± 10.2 years) who underwent both CAC scans and CMRI in the MESA baseline examination. CMRI LA volume was previously measured by human experts. Data on NT-proBNP, CHARGE-AF risk score, and the Agatston score were obtained from MESA. Discrimination was assessed using the time-dependent area under the curve.

RESULTS Over 15 years follow-up, 562 cases of AF and 140 cases of stroke accrued. The area under the curve for AI-CAC versus CMRI volumetry for AF (0.802 vs 0.798) and stroke (0.762 vs 0.751) were not significantly different. AI-CAC LA significantly improved the continuous net reclassification index for prediction of 5-year AF when added to CHARGE-AF risk score (0.23), NT-proBNP (0.37, 0.37), and Agatston score (0.44) (*P* for all <0.0001).

CONCLUSIONS AI-CAC automated LA volumetry and CMRI LA volume measured by human experts similarly predicted incident AF and stroke over 15 years. Further studies to investigate the clinical utility of AI-CAC for AF and stroke prediction are warranted. (JACC Adv. 2024;3:101300) © 2024 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

From the [a]HeartLung.AI, Houston, Texas, USA; [b]Department of Electrical and Computer Engineering, Cornell University, New York, USA; [c]Division of Cardiology, The Lundquist Institute, Torrance, California, USA; [d]Department of Radiology, Tustin Tele-radiology, Tustin, California, USA; [e]Department of Radiology, Mount Sinai Hospital, New York, New York, USA; and the [f]Heart Disease Prevention Program, Division of Cardiology, University of California, Irvine, California, USA

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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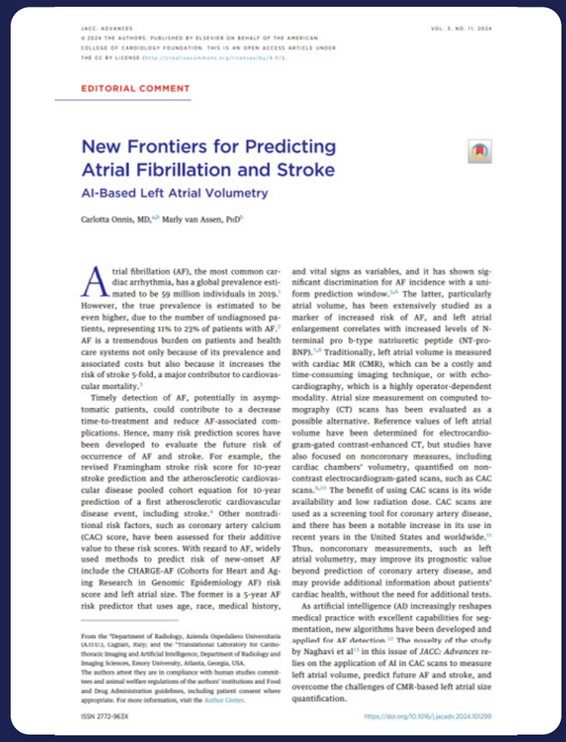
- Naghavi, M, Reeves, A, Atlas, K. et al. AI-Enabled CT Cardiac Chamber Volumetry Predicts Atrial Fibrillation and Stroke Comparable to MRI. JACC Adv. 2024 Nov, 3 (11).



JACC: ADVANCES VOL. 3, NO. 11, 2024

EDITORIAL COMMENT

New Frontiers for Predicting Atrial Fibrillation and Stroke

AI-Based Left Atrial Volumetry

Carlotta Onnis, MD,[a,b] Marly van Assen, PhD[b]

Atrial fibrillation (AF), the most common cardiac arrhythmia, has a global prevalence estimated to be 59 million individuals in 2019.[1] However, the true prevalence is estimated to be even higher, due to the number of undiagnosed patients, representing 11% to 23% of patients with AF.[2] AF is a tremendous burden on patients and healthcare systems not only because of its prevalence and associated costs but also because it increases the risk of stroke 5-fold, a major contributor to cardiovascular mortality.[3]

Timely detection of AF, potentially in asymptomatic patients, could contribute to a decrease time-to-treatment and reduce AF-associated complications. Hence, many risk prediction scores have been developed to evaluate the future risk of occurrence of AF and stroke. For example, the revised Framingham stroke risk score for 10-year stroke prediction and the atherosclerotic cardiovascular disease pooled cohort equation for 10-year prediction of a first atherosclerotic cardiovascular disease event, including stroke.[4] Other nontraditional risk factors, such as coronary artery calcium (CAC) score, have been assessed for their additive value to these risk scores. With regard to AF, widely used methods to predict risk of new-onset AF include the CHARGE-AF (Cohorts for Heart and Aging Research in Genomic Epidemiology AF) risk score and left atrial size. The former is a 5-year AF risk predictor that uses age, race, medical history, and vital signs as variables, and it has shown significant discrimination for AF incidence with a uniform prediction window.[5,6] The latter, particularly atrial volume, has been extensively studied as a marker of increased risk of AF, and left atrial enlargement correlates with increased levels of N-terminal pro b-type natriuretic peptide (NT-proBNP).[7,8] Traditionally, left atrial volume is measured with cardiac MR (CMR), which can be a costly and time-consuming imaging technique, or with echocardiography, which is a highly operator-dependent modality. Atrial size measurement on computed tomography (CT) scans has been evaluated as a possible alternative. Reference values of left atrial volume have been determined for electrocardiogram-gated contrast-enhanced CT, but studies have also focused on noncoronary measures, including cardiac chambers' volumetry, quantified on non-contrast electrocardiogram-gated scans, such as CAC scans.[9,10] The benefit of using CAC scans is its wide availability and low radiation dose. CAC scans are used as a screening tool for coronary artery disease, and there has been a notable increase in its use in recent years in the United States and worldwide.[11] Thus, noncoronary measurements, such as left atrial volumetry, may improve its prognostic value beyond prediction of coronary artery disease, and may provide additional information about patients' cardiac health, without the need for additional tests.

As artificial intelligence (AI) increasingly reshapes medical practice with excellent capabilities for segmentation, new algorithms have been developed and applied for AF detection.[12] The novelty of the study by Naghavi et al[13] in this issue of *JACC: Advances* relies on the application of AI in CAC scans to measure left atrial volume, predict future AF and stroke, and overcome the challenges of CMR-based left atrial size quantification.

From the [a]Department of Radiology, Azienda Ospedaliero Universitaria (A.O.U.), Cagliari, Italy; and the [b]Translational Laboratory for Cardiothoracic Imaging and Artificial Intelligence, Department of Radiology and Imaging Sciences, Emory University, Atlanta, Georgia, USA.

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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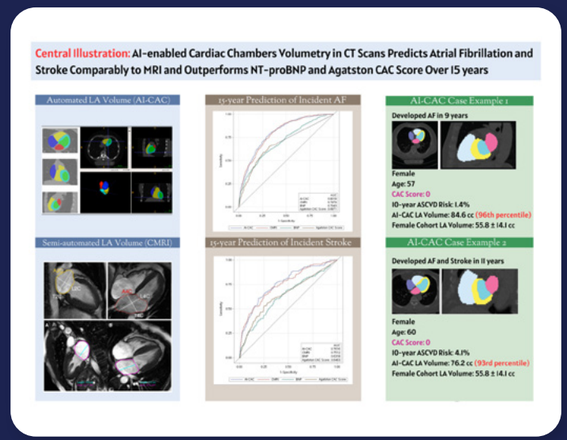
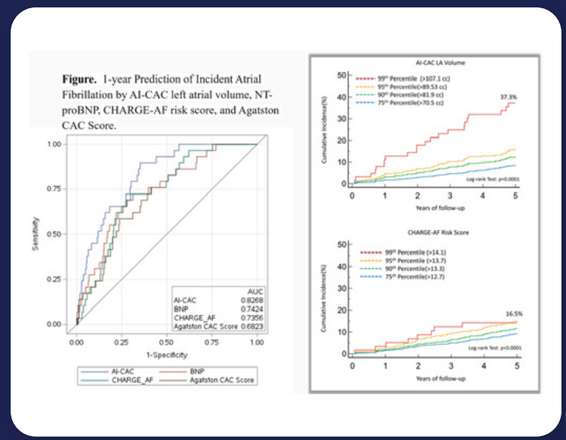
- Onnis, C, van Assen, M. New Frontiers for Predicting Atrial Fibrillation and Stroke: AI-Based Left Atrial Volumetry. JACC Adv. 2024 Nov, 3 (11).



- Central Illustration: AI-enabled left cardiac chambers volumetry in CT scans predicts atrial fibrillation and stroke comparably to MRI and outperforms NT-proBNP and agatston CAC score over 15 years.



- 1-year prediction of incident atrial fibrillation by AI-CAC left atrial volume, NT-proBNP, CHARGE-AF risk score, and Agatston CAC score.

AutoChamber™

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Direct and Indirect Revenue Opportunities for Providers

Imaging Centers
Direct Revenue

Hospitals
Indirect Revenue

AutoChamber Cash Flow Analysis		
Assumptions:		
AutoChamber HCPCS G0183 Reimbursement	**$88**	
HeartLung Fee per AutoChamber Report	**$30**	
Net Direct Revenue per AutoChamber Report	**$58**	
Percentage of High Risk for Heart Failure in Routine Chest CT Scans	**5%**	
Downstream Revenue for Workup of High Risk for Heart Failure	**$1,000**	
Percentage of Heart Failure	**0.5%**	
Lifetime Cost per Heart Failure Patient	**$109,541**	
Direct Revenue		
Chest CT Scans per Day		**100**
Yearly Gross Direct Revenue from HCPCS G0183		**$2,117,000**
Indirect Revenue		
Annual Expected Revenue for High Risk Patients		**$1,825,000**
Indirect Health Savings over 10 Years		
91 Patients Saved per year (0.5%)		**$13,290,950**

AutoChamber™

HeartLung.AI

Provider Q&A

- **Is AutoChamber™ reimbursed? If yes, what CPT code?**

  Yes, AutoChamber™ is reimbursable under the new category 3 HCPCS code G0183, with a reimbursement rate of $88.06. This code was released by CMS on April 1st, 2025, following HeartLung's application for AutoChamber™ reimbusement as an FDA-designated "**Breakthrough**" medical device.

  "New HCPCS Code Describing Software that Reports the Volume of Cardiac Chambers and Left Ventricular Wall Mass, Effective April 1, 2025. CMS is establishing a new HCPCS code, G0183, to describe a software that utilizes data from previously obtained CT scans to report the volume of cardiac chambers and left ventricular wall mass. Table 8 attachment A lists the long descriptor, status indicator, and APC assignment for HCPCS code G0183. For information on OPPS status indicators, please refer to OPPS Addendum D1 of the CY 2025 OPPS/ASC final rule for the latest definitions. This code, along with its short descriptor, status indicator, and payment rate, is also listed in the April 2025 update of the OPPS Addendum B." **https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system**

  Because AutoChamber™ uses existing CT images with no need for additional scans, radiation exposure, or patient scheduling, it's a seamless, no-brainer add-on to your current workflow. It not only enhances patient care but also creates a new revenue stream with minimal operational changes.

- **How does my PACS connect to AutoChamber™ AI cloud?**

  Your PACS can easily connect to AutoChamber™ cloud through a direct link using your unique AE title generated by HeartLung; or via a HeartLung Gateway installed and no hardware installation is required. The scanned CT images are sent from your PACS to AutoChamber™ AI cloud where the report is created and sent back to you, and is also accessible on HeartLung's Provider & Patient Portal. **https://provider.heartlung.ai**

AutoChamber™

HeartLung.AI

Provider Q&A

- **Do I need a physician's order to add an AutoChamber™ AI report to a thoracic or abdominal CT scan?**

  AutoChamber™ is designed as an opportunistic add-on service that can be applied to existing CT scans. Because it uses images that are already acquired for other medically necessary reasons, a separate physician order specifically for AutoChamber™ is not required. Nonetheless, since referring phycisians are responsible for treating patients with enlarged chambers, we strongly recommend informing and engaging all referring phycisians.

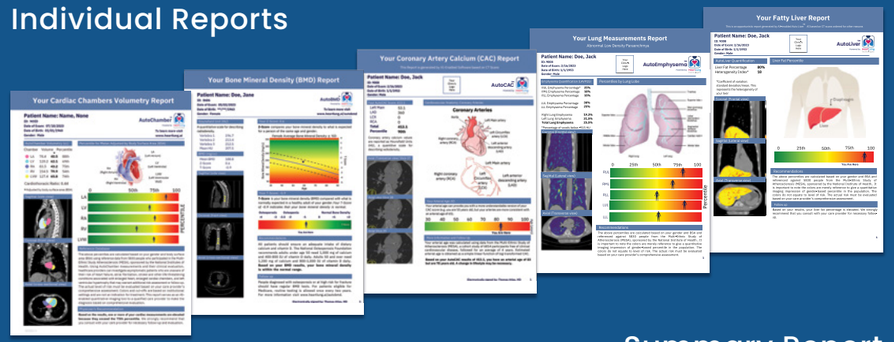
- **Which image series should I send to AutoChamber™ AI Cloud?**

  Only send one axial series to AutoChamber™ AI cloud. For example, the axial series used for coronary artery calcium scoring or lung cancer screening would work. The AutoChamber™ AI module works based on intensity (Hounsfield Units), so please send images generated using the standard convolution kernel without any modifications or reconstructions.

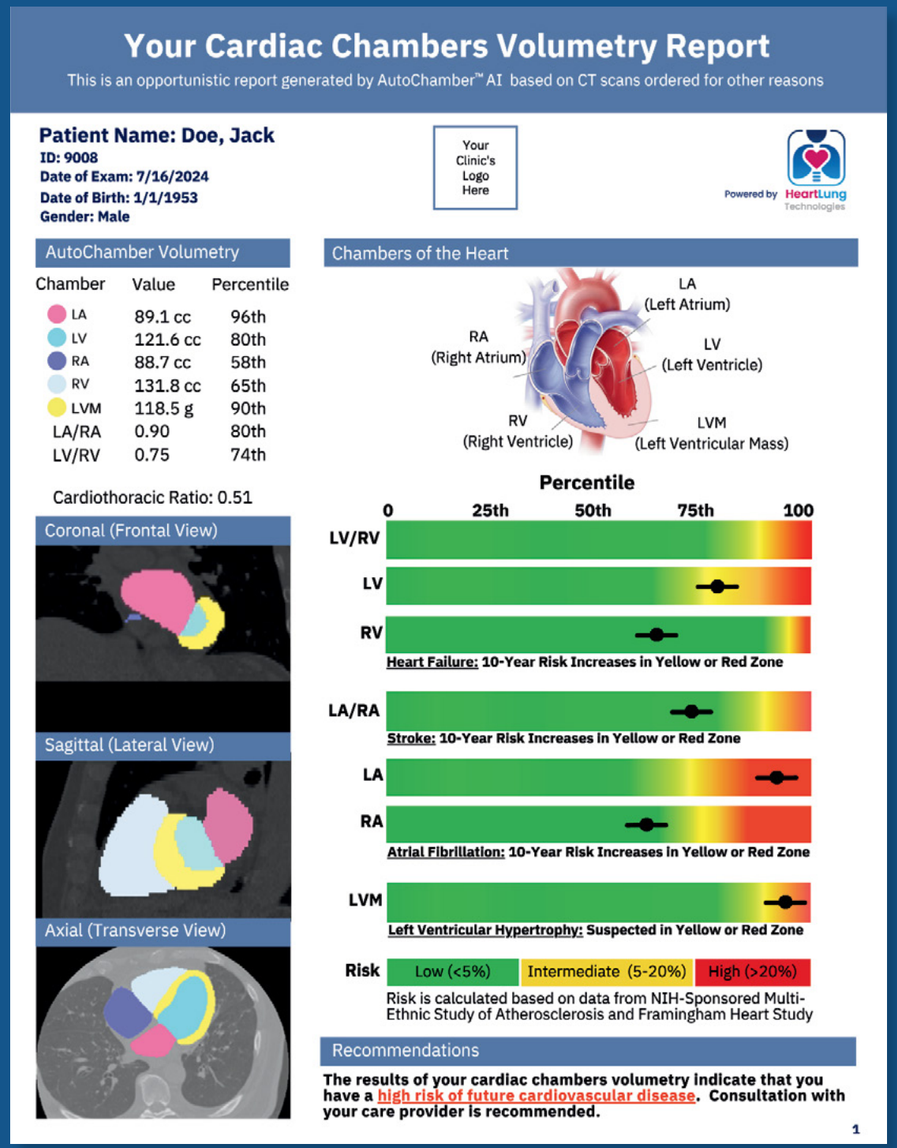
- **How do I start a free trial?**

  Simply create an account at **https://provider.heartlung.ai** and send your first set of DICOM images using the unique AE title that our system generates for your center. You will be contacted within 24 hours for verification and testing the setup.

Individual Reports



Summary Report



Your Cardiac Chambers Volumetry Report

This is an opportunistic report generated by AutoChamber™ AI based on CT scans ordered for other reasons

Patient Name: Doe, Jack
ID: 9008
Date of Exam: 7/16/2024
Date of Birth: 1/1/1953
Gender: Male

Your Clinic's Logo Here

Powered by HeartLung Technologies

AutoChamber Volumetry

Chamber	Value	Percentile
LA	89.1 cc	96th
LV	121.6 cc	80th
RA	88.7 cc	58th
RV	131.8 cc	65th
LVM	118.5 g	90th
LA/RA	0.90	80th
LV/RV	0.75	74th

Cardiothoracic Ratio: 0.51

Coronal (Frontal View)

Sagittal (Lateral View)

Axial (Transverse View)

Chambers of the Heart

LA (Left Atrium)
RA (Right Atrium)
LV (Left Ventricle)
RV (Right Ventricle)
LVM (Left Ventricular Mass)

Percentile

0 25th 50th 75th 100

LV/RV
LV
RV

Heart Failure: 10-Year Risk Increases in Yellow or Red Zone

LA/RA

Stroke: 10-Year Risk Increases in Yellow or Red Zone

LA
RA

Atrial Fibrillation: 10-Year Risk Increases in Yellow or Red Zone

LVM

Left Ventricular Hypertrophy: Suspected in Yellow or Red Zone

Risk Low (<5%) | Intermediate (5-20%) | High (>20%)

Risk is calculated based on data from NIH-Sponsored Multi-Ethnic Study of Atherosclerosis and Framingham Heart Study

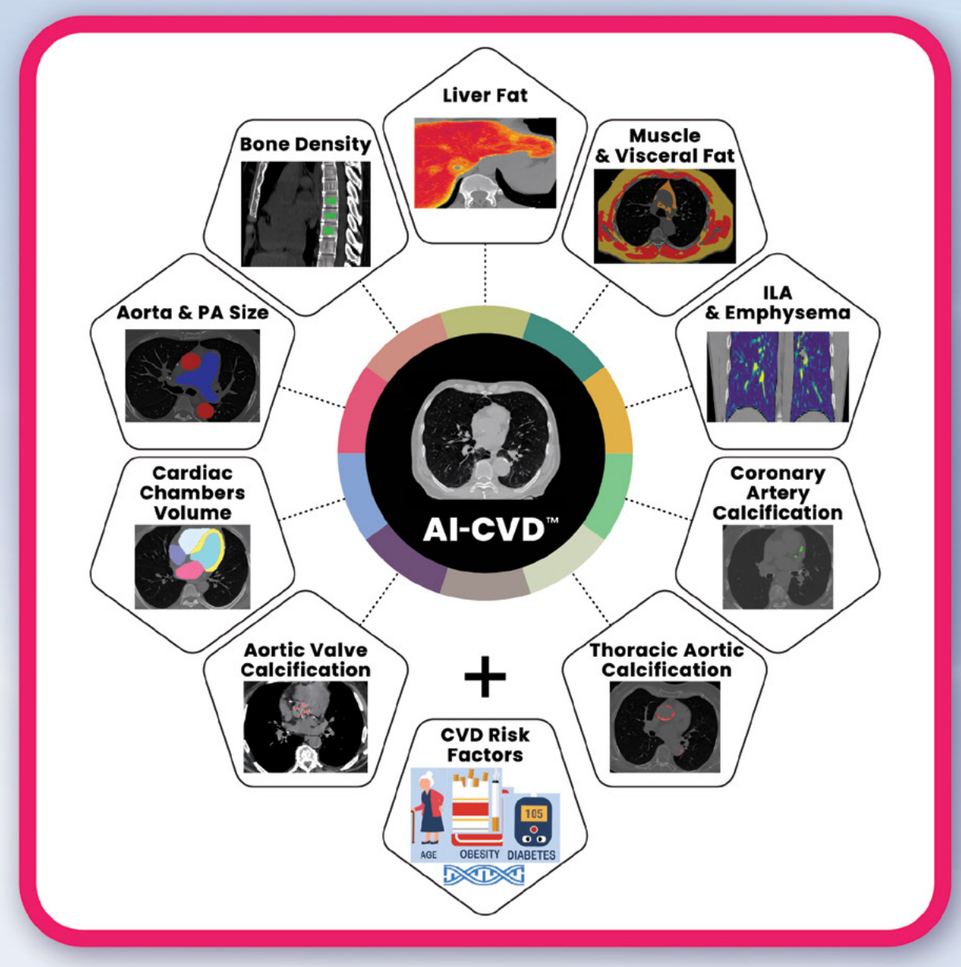
Recommendations

The results of your cardiac chambers volumetry indicate that you have a high risk of future cardiovascular disease. Consultation with your care provider is recommended.

1

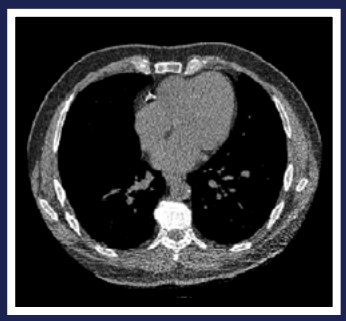
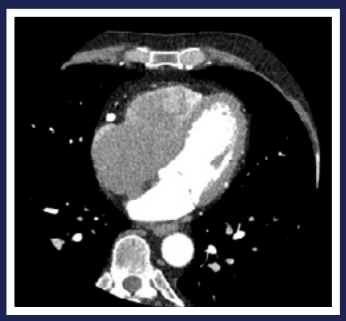
AI-CVD™

CT-BASED AI SOLUTIONS ENABLING EARLY DETECTION AND PREVENTION OF CARDIOVASCULAR DISEASE

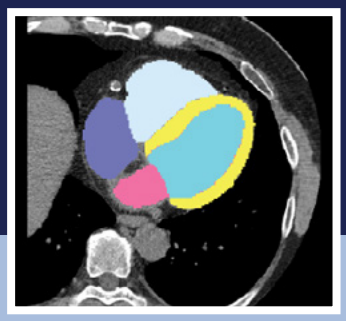
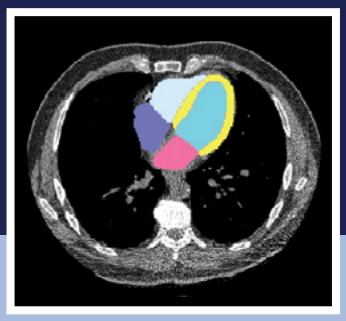
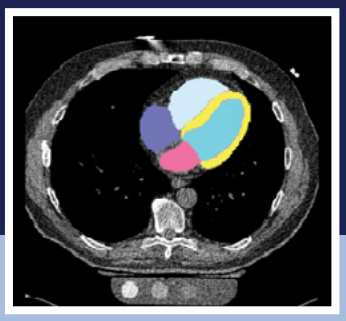
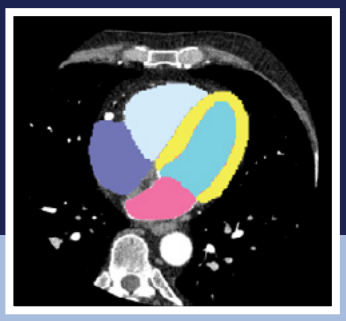


To learn more about **AI-CVD™**, which includes **AutoChamber™** Reports, scan the QR code or visit: **https://heartlung.ai/aicvd**

Before AutoChamber™

Coronary Artery Calcium Scan	LDCT Lung Cancer Screening Scan	Lung Diagnostic Scan	Coronary CT Angiography Scan
			

After AutoChamber™

Coronary Artery Calcium Scan	LDCT Lung Cancer Screening Scan	Lung Diagnostic Scan	Coronary CT Angiography Scan
			

Benefits of AutoChamber™

Opportunistic Value Generator

AutoChamber™ enables your imaging center to find life-threatening conditions in asymptomatic patients and generate revenue.

Simple and Easy Workflow Integration

Your practice can install the HeartLung gateway and receive AutoChamber™ reports directly in your PACS. Your patients can access the report from HeartLung's web portal and mobile app.

No Capital Investment Needed

Any diagnostic imaging center from anywhere in the world can sign up and start adding AutoChamber™ reports to any chest CT scans.

Rapid AI Turnaround Within Minutes

Receive rapid results within minutes of sending your scan to AutoChamber™ AI cloud. No training or learning curve is needed and no calibration phantom.

HeartLung Technologies

HeartLung Technologies Co.

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Houston, TX 77021
(310) 510-6004
www.HeartLung.ai
contact@heartlung.ai

HeartLung's AutoChamber™ is the first FDA-approved AI with "Breakthrough" designation enabling opportunistic screening and detection of hidden heart disease in CT Scans