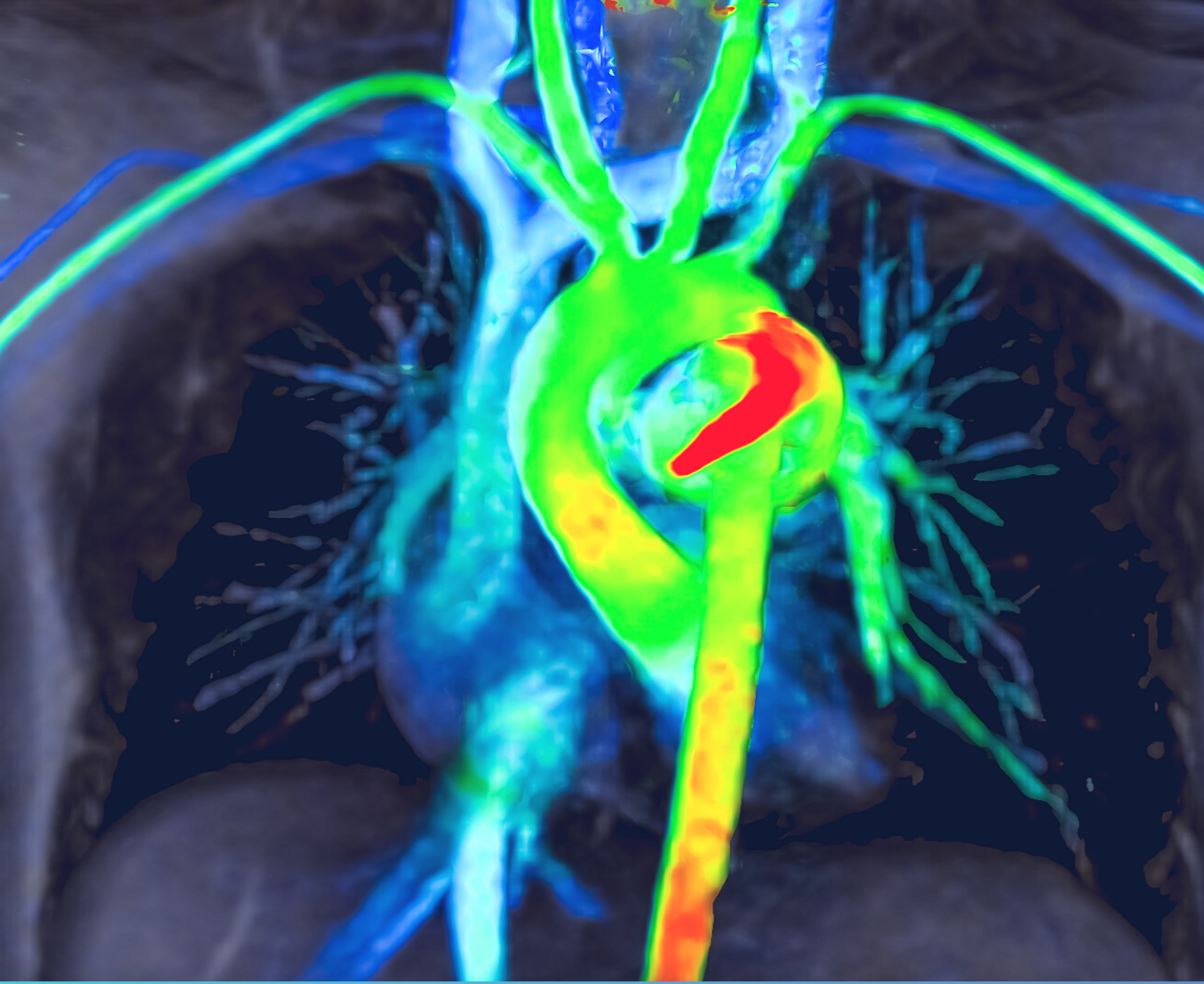


ARTERYS

Transforming Cardiac MR

Advances in AI, 4D Flow and Cloud Computing

Cardiac MR pain points

Acquisition

- Limited scanner availability
- Complex, long, error-prone exam
- Resource-intensive, requires clinician oversight

Using Cardiac MR

- Explosion of imaging data requires physician to analyze many more images
- Outdated, slow, software systems requires extensive training and maintenance

Summary

Cardiovascular Disease (CVD) is the leading cause of death worldwide.[1] To impact CVD onset and mortality rates, radiologists need access to imaging technology capable of putting fast, repeatable clinical insight within reach.

Cardiac Magnetic Resonance (MR) has commanded singular consideration within the scientific community as it provides repeatable, non-invasive measurements with image clarity and accuracy. However, Cardiac MR has traditionally been one of the most complex, timeconsuming exams to scan and analyze.

A recent study by the Mayo Clinic reported an increase of 540 percent for MR exams between 1999 and 2009.[2] Radiologists historically processed this mountain of MR images manually, increasing chances of clinical error, missed treatment insights, and clinician burnout.

This report presents an overview of Cardiac MR imaging innovations that impact radiologist productivity and clinical efficacy and examines the significant clinical, operational, and financial improvements that technological advances are achieving at imaging sites throughout the world. Technological advances include a Cardiac MR imaging innovation that uses Artificial Intelligence (AI), Deep Learning, 4D Flow, and Cloud Computing.

The diagnostic power of Cardiac MR

In a 2016 Euro Clinical Cardiac MR Registry Study

- Conducted in 57 centers
- Located in 15 European cities
- Included more than 27,000 patients

Using Cardiac MR

- Changed treatment in 62% of patients
- Provided a new diagnosis for 9% of patients
- Prevented additional invasive tests for 56% of all patients

Source: https://jcmr-online.biomedcentral.com articles/10.1186/1532-429X-15-9

Technology to Intercept a Global Killer

As CVD has spread at a steady pace over the last decade, the medical community has published statements calling for better imaging tools for diagnosis and treatment. In 2016, the American College of Cardiology's (ACC) Executive Committee and the Cardiovascular Imaging Section Leadership Council issued a report titled, "The Future of Cardiac Imaging," in which authors appealed for greater clinician, scientist and engineer collaboration to develop technology to treat this increasingly global epidemic.[3] Since the ACC report was published, researchers and vendors have made significant inroads in Cardiac MR innovation, even achieving FDA clearance and CE Marking for medical imaging technology powered by cloud computation and Artificial Intelligence.

It is not a surprise that Cardiac MR attracted research priority as it possesses clear technical advantage over other imaging modalities and is the standard of excellence in cardiac care. In 2016, the European Society of Cardiology described the power of Cardiac MR in acute and chronic heart failure treatment: "CMR is acknowledged as the gold standard for the measurements of volumes, mass and ejection fraction of both the left and right ventricles in acute and chronic heart failure treatment. It is the best alternative cardiac imaging modality for patients with nondiagnostic echocardiographic studies (particularly for imaging of the right heart) and is the method of choice in patients with complex congenital heart diseases."[4]

Despite Cardiac MR's significant technical advantages, the modality has traditionally required heavy investment of manual labor and local expertise that threatens to hinder its clinical care potential. That's why, in response to clinical demand for valuable cardiac data, various methods have been developed to simplify Cardiac MR, speed the time it takes to perform a scan, and interpret the images. Advances in 4D Flow and Artificial Intelligence (AI) have been focal points, bringing the highest potential of Cardiac MR to diagnostic sites on the front lines of the fight against CVD.

Clinical Guidelines

Increase in Clinical Guidelines Featuring Cardiac MR Medical protocol has elevated the role of Cardiac MR as new structural heart procedures assert its clinical value.[8]

The American Society of Echocardiography (ASE) published a comprehensive update for assessing all forms of valvular regurgitation to:

- Guide clinicians in best practices
- Include detailed guides for Cardiac MR[9]

The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) published updates to:

- Guidelines to use MR to diagnose, quantify, and assess valvular disease[10]

Cardiac MR acquisition

Modernizing the Cardiac MR Scan

Acquiring a Cardiac MR scan is not easy. It requires knowledge of cardiac anatomy and planes, familiarity with complex pulse sequences, and the technical skill to acquire a multiple series of images.[5] Since its introduction nearly 30 years ago, 2D Phase Contrast MR was the standard-of-care for the assessment of regional blood flow in the heart and great vessels. This method only allowed single-direction, velocity measurement evaluation of blood flow in a single, user-selected 2D slice. 2D images are highly specific in their localization, leaving no margin for error when capturing specific anatomy that has motion. 2D images make it difficult to locate anomalies even for the most well-trained and experienced technologists. Therefore, Cardiac MR scan sequences typically are performed directly by Cardiac Radiologists or with their oversight during the entire scan.

Clinical protocol required that the scan be performed during a 10-20 second patient breath hold for each slice, adding an extra obstacle during the exam. Depending on the cardiovascular problem being investigated, the challenges of traditional 2D Phase Contrast scans can prolong a cardiac scan to 60 to 90 minutes in duration. Particularly complex heart conditions often require up to an hour of scanning as multiple planes must be measured.

In contrast, 4D Flow, a new acquisition technology, clinically available by all three major MRI vendors[6], is transforming blood flow quantification and visualization. 4D Flow offers volumetric anatomical, functional, and flow information during the entire cardiac cycle during a single, freebreathing, ten minute scan.[7]

In a recent study published in Imaging, titled:*"4D-Flow MRI Quantification of Mitral and Tricuspid Regurgitation: Reproducibility and Consistency Relative to Conventional MRI"* study authors examined the local expertise necessary for evaluating patients with mitral or tricuspid valve regurgitation when using conventional multiplanar Cardiac MR vs. 4D Flow.

> *"4D-Flow has several advantages over conventional multiplanar Cardiac MRI. For example, 4D-Flow can be prescribed as a single volume acquisition that covers the entire heart, which does not require specialized knowledge of cardiac anatomy and imaging plans for acquisition," reported the Imaging study authors. "4D-Flow may simplify evaluation of structural cardiac abnormalities with MRI by reducing the workload and expertise required of the technologist performing the MRI, eliminating the need for on-site physician expertise."*[11]

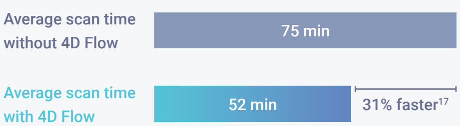
Integration of 4D Flow

Integration of 4D Flow into routine clinical practice of congenital and non-congenital Cardiac MRI—18 months experience demonstrating decreased scan times, physician monitoring and patient breath hold times. Melany Atkins, MD (Fairfax Radiological Consultants, Inova Fairfax Hospital).

Operational Impact

- Average total scan time: reduced from 75 minutes to 52 minutes, 4D Flow alone was 9 minutes.
- Total scanner time saved 88 hours: notable in adults and pediatric congenital patients.
- Local at magnet physician monitoring was not necessary: previous studies (2D Phase Contrast) required local physician oversight.

Physician time at scanner represents a potential savings of 296 hours



Clinical Impact

- 4D Flow, an invaluable tool for flow data in adult and pediatric congenital heart disease, is now integrated into routine clinical outpatient practice.
- Improvement is achieved in flow imaging with reduced failure rate compared to 2D Phase Contrast.
- The use of Fereheme allows improved contrast and resolution over Gadovist. Both agents offer the ability to evaluate flow dynamics and function in the entire 4D Flow volume set.
- The integration of 4D Flow with freebreathing acquisition has allowed [Fairfax] to image younger patients without anesthesia and reduced the need for physician monitoring.

Source: http://cmr2018.org/wp-content/uploads/2018/01/Programa-final.pdf.

Eliminating the heavy investment of time and expertise contributes to increased patient throughput and a faster scan and results in improved overall experience for patients.

Eliminating the Burden of Patient Breath Holds

4D Flow also addresses problematic patient breath holds that infamously complicate Cardiac MR exams for pediatric patients and older patients who cannot hold their breath repeatedly.[12] Image quality in a chest MRI depends on patient cooperation, mental and disease status, and patient age.[13] Even with a cooperative child, motion blurring from higher cardiac and respiratory rates threaten image integrity.[14] For this reason, the use of sedation is inevitable for children with dyspnea, younger than six years or who are mentally or hearing impaired. This is not favored by most parents and medical providers, considering recent research linking the use of general anesthesia on babies and young children to risks in brain development.[15]

4D Flow removes the problematic patient breath hold requirement in many exam circumstances. A study at Fairfax Radiology Consultants, including more than 200 patients, showed that using 4D Flow reduced the need for required breath holds from conventional 2D phase contrast images. On a number of studies, over an 18-month-period, results showed the average total exam time decreased from 71 minutes to 52 minutes. Even more remarkable, Dr. Atkins reported that 4D Flow reduced the use of anesthesia in pediatric patients.

> *"We found decreased exam time most notable in our adult and pediatric congenital population and significantly improved flow imaging with reduced failure rate compared to conventional 2D Phase Contrast," wrote Dr. Atkins. "The integration of 4D-Flow with free breathing acquisition has allowed us to image young patients without anesthesia and reduced the need for physician monitoring."*

Shorter examinations and eliminating breath holds significantly reduces costs and extends the range of diagnostic procedures that can be done routinely by MR. Shorter examinations and no breath holds may also increase reimbursements. Under the Hospital Value-Based Purchasing Program of the Centers for Medicare and Medicaid Services, patient satisfaction accounts for 30 percent of the measures of, and payments for, quality of care.[16]

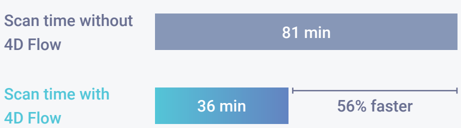
As total and operating margins average only 7 percent and 5.5 percent in 2011, a reduction in reimbursement by 1 or 2 percent can be profound. Consequentially, hospitals face real financial gains or losses if they do not optimize patients' experience during cardiac imaging.

Case Example #1: 4D Flow in Routine Clinical Practice

Figure is of a 12 year old male with a history of congenital aortic stenosis status postross. 3D rotated image from a 4D Flow series demonstrates mild pulmonicstenosis. Mild pulmonic regurgitation was also evident with a regurgitant fraction of 16%.

4D Flow scan time was 9:11. The study scan time was 36:00. Previous study performed utilizing 2D phase contrast required 1:21.00

Total time savings of 45:00.



Need picture in HD

Key 4D Flow benefits

- In less than 10 minutes, captures flow, function, anatomy
- Improves patient experience with free breathing exam
- Provides the ability to visualize and quantify flow precisely anywhere in the entire heart and great vessels
- A simple exam

In addition to operational and financial benefits of 4D Flow acquisition, there are significant clinical benefits to having the ability to visualize and quantify flow anywhere in the heart. In the Imaging study, researchers investigated the accuracy and reproducibility of volumetric 4D Flow MR interpretation for quantification of valvular regurgitation, one of the most complex diseases to quantify and assess objectively.

Unlike transthoracic echocardiography, multiplanar Cardiac MR shows “high reproducibility, better predictive power of patient outcomes for chronic regurgitation, and greater correlation with left ventricular remodeling after surgical repair,” according to the Imaging study.

> *“We have shown that quantification of mitral and tricuspid regurgitation by 4D-Flow MRI is highly reproducible and consistent across multiple measurement, with high concordance to multiplanar MRI,” wrote Imaging study authors. “Additionally, we find that measurement of regurgitant volume using either direct or indirect techniques yields equivalent results, whether performed with 4D-Flow or 2D-PC. Finally, we show that 4D-Flow volumetric technique has excellent interobserver and intraobserver reliability for quantification of regurgitant fraction and volume.”*[18]

4D Flow acquisitions provide tens of thousands of images, which can add to the ever-growing burden of radiologists. Luckily, AI and Cloud Computing can now help pre-process these large files and accelerate analysis.

Deep Learning in workflow

In 2017 Arterys receives first FDA Clearance and CE Mark for Deep Learning-based Cardiac MR product. Since then, Arterys embeds Deep Learning in other products to expand clinical availability.

An internal study concluded automated segmentation with Deep Learning accelerates exam time by up to 25 minutes.

rterys assessed Deep Learning results for accuracy using a multi-center consensus dataset for benchmarking segmentation study published in the Journal of Cardiovascular Magnetic Resonance.

Quantitative metrics (end diastolic and end systolic volumes) on unedited results from our Deep Learning automated models showed output as accurate as expert annotators from top institutions.[23]

Arterys now provides AI across the Cardiac MR workflow including:

- Function + AI: Automated LV and RV segmentation for 2D Steady-State Free Precession (SSFP) and 3D Cine Short Axis
- 4D Flow + AI: Automated landmarks and cardiac views
- Perfusion + AI: Automated LV segmentation, insertion points, and co-registration
- Delayed Enhancement + AI: Automated LV segmentation and insertion points

Source: https://jcmr-online.biomedcentral.com/articles/10.1186/s12968-015-0170-9

Cardiac MR Interpretation

The Radiologist's Gerbil Wheel

In a 2015 Applied Radiology article: *"The radiologist's gerbil wheel: interpreting images every 3-4 seconds eight hours a day at Mayo Clinic"* analyzed MR and CT use and the corresponding radiologist workload from 1999 to 2010 at the Mayo Clinic.[19] During this time, MRI exams increased from 164 images per exam to 570 images per exam, reflecting an 85 percent increase.[20]

> *"The modern radiologist must now interpret many times more examination images when compared to similar examinations performed 10–20 years ago,"* the authors wrote. *"Although these advances in sensitivity and specificity are thought to translate to improved patient care, these increasing imaging volumes are placing an ever-increasing burden on the practicing radiologists. As the workload continues to increase, there is concern that the quality of the healthcare delivered by the radiologist will decline in the form of increased detection errors as a result of increased fatigue and stress."*[21]

> *"Although these advances in sensitivity and specificity are thought to translate to improved patient care, these increasing imaging volumes are placing an everincreasing burden on the practicing radiologist,"* the Mayo study reported.

Another study published in Radiology reported that in 2006—2007, the average annual workload per radiologist was 14,900 procedures, an increase of 7 percent since 2002—2003 and 34 percent since 1991—1992.[22] The Mayo Clinic study also reported that radiologists were required to interpret almost 12 images per minute in 2010.

> *"There has been little done to mitigate the impact of increases in imaging content on workload,"* concluded the Mayo Study authors. *"The effect of increased examination content on fatigue and interpretation accuracy remains a relatively undefined clinical problem and merits additional investigation."*

Implementing Deep Learning into clinical routine

A study at University of San Diego (UCSD) analyzed 200 datasets compared to Arterys Deep Learning automated results showed good agreement between manual and deep learning methods using quantitative metrics.

Need picture
+ graphics in HD

Credit: Tara Retson, Evan Masutani (AiDA Lab, UC San Diego

Source: http://archive.ismrm.org/2018/4785.html

Artificial Intelligence Transforms Cardiac MR Interpretation

Over the last decade, the ability of computer programs to extract and interpret information from images generated by MR and CT has increased tremendously. This progress is largely attributed to the introduction of AI in radiology. First coined in 1956 by John McCarthy,[24] AI is an umbrella term that describes machines that can perform tasks that are characteristic of human intelligence. AI encompasses activities like planning, understanding language, recognizing objects and sounds, learning, and problem-solving.

For cardiac radiologists, AI can help process mountains of new imaging data and pull out relevant insights in a fraction of the time it takes to complete the same tasks manually. Capable of learning and reasoning as a human, Deep Learning, an advanced subset of AI, shows the most promise of augmenting physicians' ability to find key, relevant data presented in a concise, easily digestible format.

Deep Learning models construct neural networks that mimic the layered structure of neurons. Each layer picks out a specific feature in the data to learn. It's this layering architecture that gives Deep Learning its name and creates depth within multiple algorithm layers.[25] Through multiple layers within the neural network, Deep Learning models can process complex non-linear relationships. This renders it a powerful tool capable of analyzing large, complicated cardiac imaging data and providing new clinical insights.

Deep Learning in Clinical Practice

In the context of diagnostic imaging, Deep Learning provides time savings and increased efficiency through two different approaches to MR analysis: classification and segmentation. Classification assigns a label to an MR series—such as specific anatomical landmarks. Segmentation is the process of delineating the boundaries or "contours" of various tissues—a necessary step in determining quantitative ventricular function assessment and identifying patient pathology.[26]

Ventricular segmentation has historically been the most time consuming aspect of analyzing Cardiac MR, especially when performed manually. For conventional 2D Steady-State Free Precession (SSFP) or 3D Cine data, segmentation often requires 25 minutes per case to perform a complete manual segmentation of the left and right ventricles.[27]

Top drivers for cloud computing growth

- Increased agility, rapid scalability, and IT flexibility needed to match the external, dynamic market environment
- Integration of diverse data sets to deliver value-based care and precision medicine best enabled by cloud platforms
- Explosion in healthcare data volume and complexity
- More secure cloud environments for data protection and promise rapid disaster recovery
- Streamlining IT departments through managed cloud services

Arterys Medical Imaging Cloud AI (MICA)

The MICA platform provides collective intelligence:

- by aggregating data from around the world.
- by monitoring user input that can be used for further training Cloud computing can transcend across silos and put predictive Cardiac MR healthcare analytics within reach.

Accessing Deep Learning Power in the Cloud

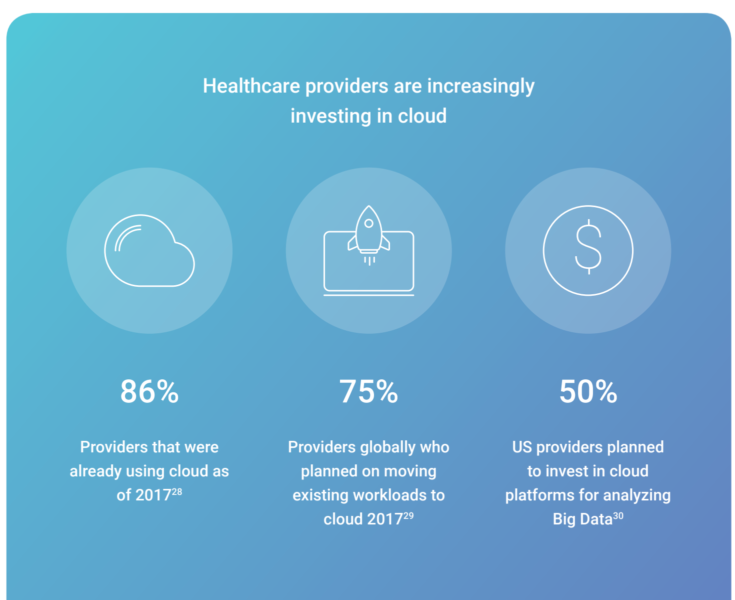
For AI to be clinically feasible, it must be fast, accurate and accessible. When clinicians put Deep Learning models to clinical use, they need instant inference, which requires multiple Graphics Processing Units (GPUs) and large computing power.

New imaging techniques like 4D Flow are also driving the need for improved computation. An average Cardiac MR exam today, for example, is about 200 MB, while data from an Arterys 4D Flow with AI exam can be up to 20 GB of data. Purchasing and maintaining this additional computing power can prove costly for hospitals. This is why a growing portion of the healthcare industry is investing in cloud infrastructure for medical imaging processing and analysis.

By nature of its architecture, cloud computing provides unlimited resources on demand, which is ideal for advanced imaging analytics. A cloud environment can also manage data sets of fluctuating size. The scalability of cloud architecture, along with its distributed computing and virtualization capabilities, ensures consistently high performance without additional costly hardware or IT investment.

Eager to leverage the benefits, healthcare organizations are increasingly investing in the cloud to avoid the upfront cost and complexity of owning and maintaining their own IT infrastructure. Eighty-six percent of healthcare providers were already using the cloud in 2017. Approximately 75 percent of providers around the world planned to move existing workloads to the cloud in 2017, and 50 percent of U.S. providers planned to invest in cloud platforms for analyzing Big Data.

A recent study examined the computing value of cloud-processed Cardiac MR imaging for pulmonary 4D Flow quantification. Over a period of one year beginning in July 2014, researchers recruited 52 patients planned for Cardiac MR. After the exam, raw data was uploaded directly from the MR scanner to a dedicated Arterys system in the cloud and transformed into DICOM data.



Security for PHI

The Arterys system safeguards Patient Protected Health Information (PHI). When accredited users of the system, such as authorized medical staff, request personal records such as imaging data or analytical results, data retracted from the Arterys cloud and rebuilt with PHI from the hospital's secure server.

From the Scanner to the Arterys Cardio AI analysis, the Edge Service provides seamless integration and access to clinical data, while protecting patient privacy.

Arterys cloud computing provides preeminent secure data analysis in the cloud and complies with local legal and data privacy requirements.[32]

Arterys Cardio AI[MR] differentiators

Arterys cloud post-processing is a complete solution for routine Cardiac MR post-processing with AI automation for increased efficiency.

An innovative imaging infrastructure

Only web-based Cardiac MR with a Medical Imaging Cloud AITM (MICA) platform:

- speed and consistently high performance regardless of image size
- fast, scalable infrastructure for supercomputing and big data analytics
- no investment in hardware
- all you need is internet and our URL

The only post-processing solution applying Deep Learning across the Cardiac MR workflow for faster analysis and overall increased efficiency: saving up to 25 minutes for short axis ventricular segmentation.

After raw image data was de-identified in a HIPPA-compliant manner, the Arterys system applied its cloudbased image reconstruction, data correction, and real-time interactive 3D post-processing tools for function and flow quantification. Once this data processing was complete, cloud tools performed flow visualization, quantitative analysis, and statistical analysis.

The results were remarkable. The visualization, quantification, and data interpretation required a mere 12 minutes per patient.

> *"In this Cloudprocessed 4D CMR flow imaging for pulmonary flow quantification study, we demonstrated that bulk flow and pulmonary regurgitation can be accurately quantified using 4D-Flow imaging analyzed with a cloud based application,"* wrote the study authors.[31]

Cloud computing also allows sites to expand their reach while centralizing and standardizing their expertise, especially for large, multi-site locations. This simplifies and streamlines multi-center collaboration as colleagues or an interdisciplinary team can share results for a second opinion with a single click.

Data Health Security and Cloud Computing

The healthcare community's embrace of cloud computing reflects advances in securing PHI in the cloud.

Deep Learning, Cloud Computing and Predictive Analytics

Cloud computing enables 4D Flow and AI for accurate, faster postprocessing, and invites the use of predictive analytics in clinical treatment of CVD. Predictive analytics applies statistical analysis techniques and automated Deep Learning algorithms to data sets to create predictive models that place a numerical value on the likelihood of a particular event happening. In the context of CVD, predictive analytics tools can, for example, forecast the likelihood a patient will develop further complications and allow providers to tailor treatments and services with prevision.

Numerous healthcare organizations, including the ACC, have encouraged the convergence of predictive analytics and Deep Learning. In their 2016 report, "The Future of Cardiac Imaging," ACC authors wrote:

An FDA-cleared comprehensive 4D Flow and CE Marked comprehensive 4D Flow

Visualization and quantification anywhere on the heart. More informed treatment decision.

Increased accessibility and collaboration

Access data anytime, anywhere. Share with colleagues with a single click to:

- inform referring physicians
- get a second opinion
- collaborate for multi-center research

Exclusive PHI data protection

Clinician can access patient data, while PHI remains within hospital network

Software as a Service (SaaS)

Protect your investment. Receive latest features instantly.

> "The ACC and other imaging societies should collaborate with big data scientists and bioinformatics experts to expedite ways of using imaging data across multiple modalities to validate the value of cardiac imaging in improving healthcare outcomes. New precision medicine algorithms can help data-driven discoveries and identification of patient phenotypes through the study of clinical and imaging data interactions. Moreover, the use of a machine-learning interphase can help automate the analysis and create predictive analytics through algorithms that detect and learn from complex relationships and patterns."[33]

Conclusion

Cardiac MR is often the most sensitive technique for important clinical measurements used to diagnose and treat CVD. Currently, lengthy and costly acquisition times limit its use.

Fortunately, technological advances have emerged to help simplify the current Cardiac MR protocol and unlock its potential. Unleashing the power of AI and 4D Flow on the imaging world's mountains of patient data could speed up diagnoses and make clinical care more data-driven, intelligent, and patient-focused. Most importantly, cutting-edge Cardiac MR can get patients on the path to recovery much sooner.

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