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Panorama

Point-of-Care Ultrasound With Artificial Intelligence–Driven Diagnostics in Giant Cell Arteritis: Blindness Prevention on a Global Scale

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Giant cell arteritis (GCA) is the most common autoimmune systemic vasculitis of older adults.[1] Typically, it affects individuals 50 years and older, and more women than men. The lifetime risk of GCA for women is 1% and 0.5% for men. Data suggest that the incidence of GCA is highest in Scandinavian populations but is relatively low in Southern European populations. The incidence of GCA varies between 18-29 per 100,000 in those aged ≥ 50 years but it is between 41 and 113 per 100,000 in Europeans.[2] By 2050, over 3 million are projected to be diagnosed with GCA, and blindness related to the disease is expected to reach half a million worldwide.[3] Between 2014 and 2050, the financial burden associated with GCA-related visual impairment and treatment costs due to the side effects following treatment with steroids could reach US $77 billion and $6.6 billion, respectively, in the United States.[4]

In the United Kingdom alone, 10/100,000 may be affected by GCA, and its incidence rises with age. Fast-tracking diagnostic pathways and raising public awareness to complications of preventable blindness and stroke from GCA need to be done akin to "get with the guidelines" (GTWG) stroke quality improvement measures created by the American Heart Association and the American Stroke Association. In many countries, "fast-track clinics" have been established to facilitate the early diagnosis of GCA and use point-of-care ultrasound (POCUS), which essentially consists of ultrasonography performed in clinic in real time. However, in a retrospective cohort study done in the Netherlands, the median time after onset of symptoms to a fast-tracked clinic was 31 days.[5] Those with isolated cranial GCA had a median delay from symptom onset to treatment of 21 days; this delay was 57 days when extracranial large vessel involvement was present.[5] This is proof that fast-track clinics cannot prevent blindness associated with GCA unless a rapid/on-the-spot diagnosis follows acquisition of data to facilitate treatment initiation. It is therefore time to move GCA to a "stroke of the eye" category or risk blindness in a significant percentage of patients owing to delayed treatment or diagnosis. To date, there is not a single protocol for *prevention* of blindness in GCA anywhere across Europe or North America. A universal protocol based on a centralized cloud-based data collection system modeled on POCUS data acquisition and an artificial intelligence (AI)-driven diagnostic platform that provides instantaneous results for a clinician are urgently needed to prevent blindness.

Currently, there are no consistent guidelines for general practitioners, rheumatologists, neurologists, or ophthalmologists that recommend a specific pathway to use ultrasound as a screening tool for patients with symptoms suggestive of GCA in adult patients (age ≥ 50 yrs). Patients with GCA symptoms are a treatable clinical emergency if the symptoms are correctly identified.

Viz.AI is a state-of-the-art and US Food and Drug Administration (FDA)-cleared AI-based technology that can autodetect large vessel occlusion in stroke; its platform leverages FDA-cleared algorithms to analyze medical images and data, echocardiograms, and electrocardiograms to accelerate diagnosis and treatment. In fact, Viz Vascular helps detect clot detection and automated right ventricle/left ventricle ratio in pulmonary emboli, as well as provide point-of-care algorithms for detection of aortic aneurysms. There is no reason why POCUS combined with AI algorithms cannot do the same for GCA.

Modern portable ultrasound scanners offer anonymized, Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant, and cloud-based data collection and retrieval; if automated classification of images is modeled using AI, a rapid diagnosis is feasible. The widespread commercial availability of handheld probes and pocket ultrasound transducers makes it feasible to acquire images at the bedside across many clinical scenarios. The probes are typically portable, lightweight, affordable, and easy to use, and given technological innovations that have been incorporated by manufacturers, reduce cost and complexity.

Real-time data collection using a single probe that spans multiple frequencies (1-10 MHz) eliminating the use of multiple piezoelectric probes used in a traditional ultrasound machine has been described. The POCUS data were compared against a standard ultrasound unit—considered the gold standard—and the authors demonstrated that a handheld probe was comparable.[5]

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Since POCUS devices possess the capability to synchronize and upload images to web-based cloud servers compliant with HIPAA, real-time feedback to the operator regarding image acquisition is an advantage that nullifies operator-dependent technical issues. In general, POCUS can be used anywhere—in an ambulance or on the field—and image interpretation, specifically in underserved areas, can be instantaneous based on AI algorithms. In acute GCA, the typical findings on ultrasound are a noncompressible, hypoechoic halo accompanied by concentric thickening of the arterial wall. Although temporal artery biopsy (TAB) was the diagnostic gold standard for GCA, low sensitivity is a concern.

Temporal arteries are superficial, and they are unaffected by overlying structures. Since machine learning (ML), deep neural networks, and AI-driven algorithms have already been applied to study atherosclerosis in cardiovascular diseases and imaging of the carotids, the diagnostic landscape has evolved considerably, and detection, segmentation. and classification of atherosclerotic disorders has already been established. Last, unsupervised classification is a technique that is fully automated and does not leverage any training data, negating the need for a priori diagnosis by a radiologist or ultrasonographer. It allows ML algorithms to analyze and cluster unlabeled data sets by discovering hidden patterns or data groups without human intervention and can detect pathologies associated with various diseases.

According to the 2022 European Alliance of Associations for Rheumatology criteria for diagnosis of GCA, a halo sign on ultrasound alone makes for 83% of the diagnostic score if phenotypic criteria are met. Patients presenting to the emergency department, urgent care centers, or clinics with neurology/optometry/ophthalmology services with de novo vision symptoms with or without heterogenous phenotypic features indicative of GCA, such as jaw pain with or without new-onset headache that may or may not be localized to the temple, upper limb claudication, cutaneous allodynia, scalp tenderness or posterior circulation stroke, need to be evaluated for a diagnosis using POCUS and AI-driven algorithms. Obviously, mimics need to be excluded by an eye exam, including fundus evaluation for retinal detachment or tears, which is fundamental to screening patients for GCA.

The absence of a halo sign for GCA[6] carries a negative predictive value of 96% and practically rules out a diagnosis of GCA; the need for a biopsy is minimal. Factors influencing sensitivity include the presence of bilateral halos (enhancing sensitivity) and prior corticosteroid use (reducing sensitivity). Additionally, quantitative measures like halo counts and halo scores provide insights into disease severity, complication risks, and treatment response. Regression of the halo sign, an indicator of improvement, occurs at different rates in the superficial temporal artery and axillary artery following immunosuppressive treatment. Combining multiple imaging modalities in diagnostic algorithms can achieve a perfect balance of sensitivity and specificity (100%). The diagnostic gold standard for GCA diagnosis[7] was TAB, but it is expensive, carries a false-negative rate of 60%, and is invasive. Delay in diagnosis is unavoidable with use of TAB. A prospective multicenter cohort study[8] (Temporal Artery Biopsy vs Ultrasound in Diagnosis of Giant Cell Arteritis [TABUL]) compared TAB to ultrasound of temporal and axillary arteries.[9] Results showed that ultrasound outperformed TAB (54% vs 39%) in those with GCA previously identified by biopsy; however, specificity was lower (81-100%). It is a balance between acceptance of a higher sensitivity vs a lower specificity, assuming that the TAB is the gold standard. Traditional TAB has limitations,[9] including a high false-negative rate of 60% in patients with an established GCA diagnosis. Delays in obtaining a tissue biopsy, skip lesions, inadequate sample length biopsy, and incorrect sampling of tissue are some of its drawbacks. Delay equals blindness in GCA care.

Finally, a retrospective study done between 2017 and 2019 used a segmentation technique using U-Net convolutional neural network to create and analyze training, validation, and test sets, and reported that the area under the curve was 0.931 and 0.835 on the validation and test sets, respectively.[8] The authors noted that acquisition modalities and the presence of thrombus could have interfered with their results, which demonstrated a specificity of 95% and a sensitivity of 60% for the test set, when an image positivity threshold was determined by focusing on specificity. This study reveals for the first time that the diagnostic criteria for GCA can be changed.

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