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THE DIAGNOSTIC ACCURACY OF VASCULAR ULTRASOUND IN PATIENTS SUSPECTED OF GCA: A DANISH MULTICENTRE PROSPECTIVE COHORT STUDY

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Background: Giant Cell Arteritis (GCA) is one of the most common systemic vasculitis. Temporal artery biopsy (TAB) has been the standard test to confirm the diagnosis of GCA. However, TAB has a lower sensitivity than clinical diagnosis and up to 44% of biopsy-negative patients are clinically diagnosed as having GCA. In a recent meta-analysis of the diagnostic performance of ultrasound (US) in GCA the sensitivity was 77 % (1). The included studies were performed by expert groups in single centres. In the to date only multicentre study (TABUL) investigating the diagnostic accuracy of US compared to clinical diagnosis after 6 months the sensitivity was lower (54%) (2)

Objectives: To evaluate the diagnostic accuracy of vascular US compared to TAB in a multicentre study.

Methods: In three Danish centres patients suspected for GCA were included during a period of two years. At baseline, clinical and laboratory data were collected and vascular US of temporal, facial, common carotid and axillary artery were performed. The US examinations were performed with high frequency transducers (15-18 MHz) and followed by a TAB. All ultrasonographers had participated in the same standardized US educational program and were blinded to clinical and laboratory data. An external expert blinded to clinical and laboratory data evaluated all images and made the final US diagnosis.

A positive sign for vasculitis in cranial arteries was defined as a hypoechoic intima media complex (IMC) thickening (halo sign) and a positive compression sign. A homogeneous IMC increased thickness in axillary artery of $\geq 1\text{mm}$ and in common carotid artery $\geq 1.5\text{mm}$ was defined as vasculitis.

The consultant rheumatologist's diagnosis at 6 months after initial presentation was considered as the reference standard for the diagnosis of GCA.

Results: During the recruitment period, 112 patients were included, 59% females, mean (SD) age 72.4(7.9) years, among which 91(81.3%) fulfilled the ACR 1990 classification criteria for GCA. 92% of the patients reported a newly emerged localized headache, while 49 (43.8%) experienced polymyalgia rheumatic symptoms. TAB was positive in 46(41.1%) and inconclusive in 6 patients, who were excluded from the analysis. Mean (SD) duration of glucocorticoid therapy prior to US and TAB was 0.91(1.55) and 4.02(2.61) days, respectively. In 62 patients, the final diagnosis was GCA.

In all patients with a positive TAB, the US of the temporal artery was also positive for GCA. Of 19 cases with positive US and negative TAB, 12 were clinically diagnosed with GCA of whom 6 had isolated large vessel involvement on US. Among 41 patients with both negative US and TAB, 4 were clinically diagnosed with GCA (Box 1) US had a sensitivity of 93% and specificity of 84% for the diagnosis of GCA, while the sensitivity for TAB was lower (74%) with a specificity of 100%. For the diagnosis of GCA, US had a PPV of 89.2 % and a NPV of 90.2%, while for TAB the PPV was 100% and the NPV 73.3%.

Conclusion: US evaluation of the temporal, facial and selected supraaortic arteries performed by trained ultrasonographers can replace biopsy in the diagnosis of GCA.

Box.1

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OCULAR MORBIDITY IN PATIENTS WITH PMR AND GCA IN THE UK - A CPRD STUDY

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Background: Visual loss is the most serious consequences of a diagnosis of polymyalgia rheumatic (PMR) and giant cell arteritis (GCA). To date, information on the occurrence of eye disease in GCA has been based almost exclusively on small hospital-based patient series. Furthermore the lack of control group for these studies results in a lack of relative risk estimates for visual loss.

There are no accurate data on the prevalence and nature of eye complications among patients in the community. Patients with GCA may be exclusively managed in the primary care setting without referral for either temporal artery biopsy or ophthalmic department examination. Currently the incidence and prevalence of eye complications within this group are unknown.

Objectives: Examine the absolute rate and relative risk of ocular morbidity, in a longitudinal community setting, in patients with PMR and or GCA including visual loss, AOIN including optic atrophy, cataract and glaucoma identified from Read codes in the (Clinical Practice Research Datalink) CPRD dataset.

Methods: Construction of a disease cohort of incident diagnoses of PMR and GCA from patients in the CPRD matched to controls on age, sex (+/- 2 years) and practice location. Diagnosis were identified by CPRD researchers of those individuals between January 1997 to December 2015, with a minimum age at diagnosis of 50 years. Those with both a diagnosis of PMR and GCA were analysed in the GCA group. The outcomes of ocular morbidity included Read codes for severe visual impairment (multiple codes covered: blindness, severe visual impairment, registered partially sighted, issue of certificate of visual impairment, examination findings of 4/60 or worse), anterior ischaemic optic neuropathy (including codes of optic neuropathy and atrophy but not codes of glaucomatous atrophy), cataract, cataract extraction and glaucoma. Statistically modelling with Cox proportional hazards was used to generate hazard ratios for ocular morbidity taking account of censorship through death and moving out of area.

Results: We identified 30,714 individuals with PMR (20,270 women; 66%) with a mean age at diagnosis of 72.9 year (sd 9.1) and 6,104 with GCA (4,309 women; 70.6%) with a mean age of 72.1 years (sd 9.4). Of those diagnosed with GCA 1,669 were also diagnosed with PMR. Using Read codes for severe visual impairment and blindness 5.9% of patients with GCA and 2.7% with PMR had this complication compared with 1.6% of the matched controls. The hazard ratio for the various ocular morbidities and by cases of PMR or GCA are shown in the table below:

Ocular morbidity	PMR HR (95% CI) p value	GCA HR (95% CI) p value
Severe visual impairment	1.76 (1.60, 1.94) p<0.001	3.55 (3.10, 4.08) p<0.001
Anterior ischaemic optic atrophy	3.37 (2.15, 5.31) p<0.001	36.33 (25.19, 52.39) p<0.001
Cataract	2.18 (2.04, 2.32) p<0.001	2.48 (2.22, 2.78) p<0.001
Cataract operation	2.11 (1.97, 2.25) p<0.001	2.41 (2.13, 2.72) p<0.001
Glaucoma	2.10 (1.91, 2.32) p<0.001	2.50 (2.10, 2.97) p<0.001

Conclusion: These community-based national data on risk of ocular morbidity in PMR and GCA show for the first time the risk of various ocular morbidities are increased for both groups. In addition this are the first estimates of relative risk compared to an age and sex matched population. These data are crucial