Performance of a Fast-Track Pathway for Giant Cell Arteritis in Waikato, Aotearoa New Zealand

Giant Cell Arteritis is a large vessel vasculitis which is the most common primary vasculitis in adults over 50 years of age. Ischaemic complications can arise, including visual loss, which can be permanent. Early accurate diagnosis and prompt treatment is therefore critical.

Historically, temporal artery biopsy has been the primary means of diagnosis, however, in recent years there has been focus on colour doppler ultrasound (CDUS) of the temporal and axillary arteries with particular interest in its low cost and availability [1, 2]. Numerous meta-analyses support the performance of CDUS in the diagnosis of giant cell arteritis [1, 3-9].

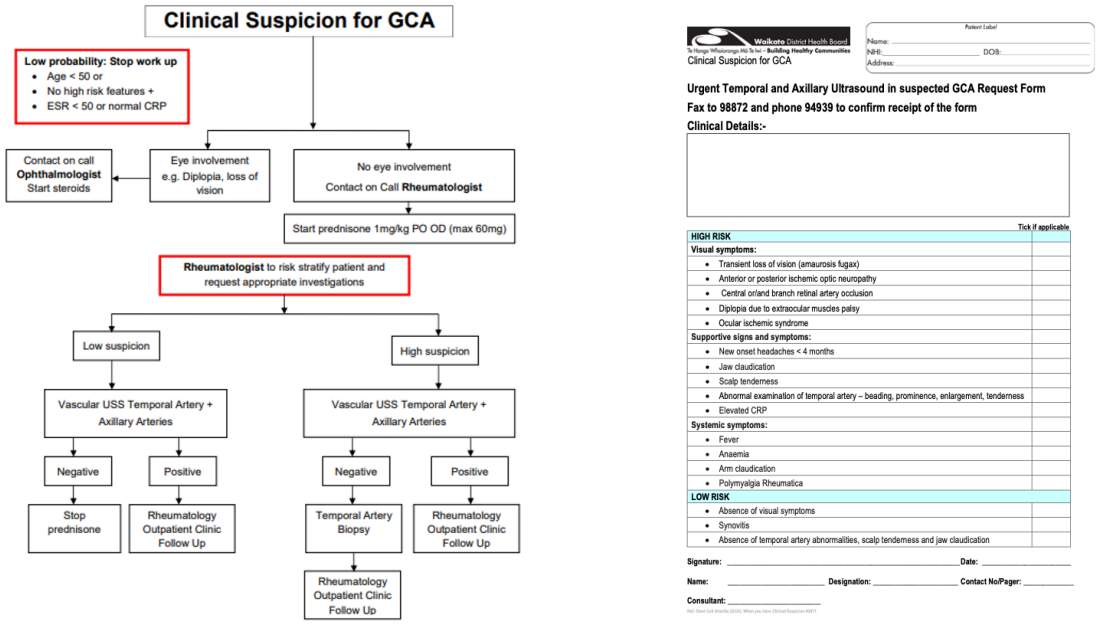
Fast-track pathways in Giant Cell Arteritis aim to have a risk assessment by a specialist (usually a Rheumatologist or Ophthalmologist) performed at the time of referral with a CDUS organised for the same day or next working day. Decisions regarding further tests and the need to continue corticosteroids are made rapidly, reducing harms of treatment or investigations to patients. The benefits of fast-track pathways include less visual loss, reduced time to diagnosis and less temporal artery biopsy requests [2, 10-13]. Fast-track pathways also support Primary Care physicians who have highlight access issues in the rapid investigation of patients with suspected Giant Cell Arteritis [14].

Most of the data on fast-track pathways do not take into consideration “real-world” practice. This is where our study is beneficial in reflecting the practical aspects of implementing a fast-track pathway for Giant Cell Arteritis in the hope of guiding other healthcare centres in the design of their own pathways.

Methods:

The Rheumatology Department at the Waikato Hospital set up a Giant Cell Arteritis fast-track pathway at the end of 2013 (Figure 1) in collaboration with the Ophthalmologists. Patients suspected of having Giant Cell Arteritis were referred via telephone from Primary Care physicians, Specialists or inpatient teams to either Ophthalmology (if visual symptoms were present) or Rheumatology (if no visual symptoms).

Figure 1. The protocol for the GCA fast-track pathway at the Waikato Hospital, Aotearoa New Zealand



NB: GCA = giant cell arteritis; ESR = erythrocyte sedimentation rate; CRP = C-reactive protein; PO = oral; OD= daily; USS = ultrasound scan;

If the risk of Giant Cell Arteritis was assessed as sufficient, a CDUS of the temporal arteries was requested, which would usually be done on the day of or next day after the referral. If the referral was made out of hours, corticosteroids would be commenced at the discretion of the on-call specialist. Following the CDUS, the specialist would make a decision regarding further investigation (i.e., temporal artery biopsy) and on appropriate follow up.

Ultrasound examinations were performed by experienced vascular ultrasonographers with Postgraduate or Master's level qualifications. The protocol involved scanning both temporal and axillary arteries. Ultrasound early in the study period was performed using the GE Logiq 9 or Philips IU22 ultrasound system with transducers of operating frequency 3-9MHz or 5-17MHz. Over the course of the study period, newer ultrasound systems and transducers were used. By 2021, there was an upgrade to GE Logiq 10 and Philips EPIQ (with higher frequency transducers of 4-18MHz or 3-12MHz). When scanning temporal or axillary arteries, the highest frequency transducer for adequate penetration was chosen.

Cases in the fast-track pathway have been collected prospectively from January 2014 using the referral request for CDUS. The requests from January 2014 to December 2022 were reviewed retrospectively to gather data on clinical symptoms, laboratory results and to generate a list of all cases in the fast-track pathway. The electronic records for each case were searched to collect information from referrals, results of investigations, treatment received by the patient and the final clinical diagnosis noted by the treating physician. In order to capture all patients going through the fast-track pathway, we also searched ultrasonography lists for patients who had a CDUS requested over this time period. If the CDUS occurred alone or prior to a temporal artery biopsy, then it was considered part of the fast-track pathway.

Temporal artery biopsy lists were also collected for the three years prior to the pathway to appreciate the rate of biopsy use prior to implementation of the pathway.

Ethnicities have been reported in conjunction with the New Zealand Statistics (NZ Stats) reporting [15] and where patients identified with two different ethnicities (commonly Māori and New Zealand European), both were counted, thus giving a total percent as greater than 100%. This is consistent with how NZ Stats report their census data.

Given the pre-test probability of Giant Cell Arteritis was not often clear from the records, a risk score was applied dividing patients into risk categories using an externally validated probability score established by Ing et al [16]. This includes age, gender, clinical symptoms (i.e., new headache, temporal artery tenderness or reduced pulse, jaw or tongue claudication, diplopia or typical visual loss) with erythrocyte sedimentation rate (ESR), C-reactive protein (CRP) and elevated platelets above upper limit of normal. Based on these factors, a probability of having Giant Cell Arteritis score was generated organising patients into very low risk (<2.7%), low risk (<7%), moderate risk (<23%), high risk (<43%) and very high risk (> 43%). This score appears to assist in the triage of patients with suspected Giant Cell Arteritis though not without fault ([16, 17].

CDUS was classified as positive if the halo sign was present (defined as a hypoechoic ring around the lumen of the temporal or axillary artery) and indeterminate if only wall thickening was noted according to the radiology report. Temporal artery biopsy was classified as positive if there was evidence of active inflammation consistent with Giant Cell Arteritis and the histopathologist's report was supportive of active Giant Cell Arteritis. If there was a suggestion of possible past arteritis, this was not included as a positive temporal artery biopsy.

Statistical Analysis

Descriptive data are presented as frequencies for categorical variables. Continuous variables are presented as mean with standard deviation (SD) and median with interquartile range (IQR). Where symptoms were not reported, this was reported as missing data, thus percentage calculations are valid percent rather than total percent. Student T-tests or Welch's T-test were performed where appropriate as were non-parametric tests (Mann Whitney U test). All analyses were conducted in IBM SPSS 29 (New York, United States). All significance tests were two-tailed and p values of less than 0.05 were considered significant.

Results

Between January 2014 and December 2022, there were 664 patients who were referred through the fast-track pathway with 648 individual patients. There were 16 duplicate episodes which have been excluded from analysis but are detailed in the appendix.

Baseline Characteristics

Patients managed through the fast-track pathway had a mean (SD) age of 70.5 (11.0) years and 69.3% were female. The age range was 17 to 96 years with 25 patients (3.8%) being less than 50 years of age. Ethnicity, clinical and laboratory features are detailed further in Table 1.

Table 1. Clinical characteristics of patients in the fast-track pathway.

	FTP (n=648)
Ethnicity No. pts (%)	
European	553 (85.3)
Māori	63 (9.7)
Pacific Islander	7 (1.1)
Asian	9 (1.4)
MELAA	4 (0.6)
Other	10 (1.5)
Not stated	10 (1.5)
Total	(101.1)
Clinical Features	
Days of symptoms – median (IQR)	14.0 (6 to 30)
Symptoms – no./valid no. (valid %)	
Headache (any)	565/617 (91.6)
Headache (unilateral)	288/617 (46.7)
Scalp Sensitivity	278/461 (60.3)
Jaw Claudication	162/486 (33.3)
Visual symptoms (any)	219/488 (44.9)
Typical Visual symptoms (AION, PION, CRAO)	21/648 (3.2) ‡
Diplopia	20/648 (3.1) ‡
PMR symptoms	171/375 (45.6)
Temporal artery abnormality†	252/392 (64.3)
Laboratory Features – no./valid no. (valid %)	
Haemoglobin g/L	
<115 (women)	66/426 (15.5)
<130 (men)	65/176 (37.0)
Platelets >400 (%) x10^9/L	101/616 (16.4)
ESR mm/hour	
mean (SD)	30.6 (26.5)
median (IQR)	23.5 (10 to 41)
CRP mg/L	
mean (SD)	40.9 (66.0)
median (IQR)	10.0 (2.5 to 53.0)
ACR 2022 Criteria Score – No. (%)	
6 or more	365/638 (57.2)
Less than 6	273/638 (42.8)
Risk using Ing Risk Score (16) No. pts (valid %) n=503	
Very low < 2.7%	37/503 (7.4)
No. with GCA (% of risk group)	2 (5.4)
Low < 7 - 2.7%	152/503 (30.2)
No. with GCA (% of risk group)	10 (6.6)
Moderate < 23 - 7.0%	171/503 (34.0)
No. with GCA (% of risk group)	34 (19.8)
High <43 - 23.0%	69/503 (13.7)
No. with GCA (% of risk group)	30 (43.5)
Very high ≧ 43%	74/503 (14.7)

No. with GCA (% of risk group)	53 (71.6)

FTP = fast track pathway; MELAA = middle eastern, latin America, African ; IQR = interquartile range; AION = anterior ischaemic optic neuropathy; PION = posterior ischaemic optic neuropathy; CRAO = central retinal artery occlusion; PMR = polymyalgia rheumatica; ESR = erythrocyte sedimentation rate; CRP = C reactive protein; ACR = American College of Rheumatology; GCA = Giant Cell Arteritis

† Temporal artery abnormality – either decreased pulse or tenderness.

‡ % calculated as number of typical symptoms out of the total number of patients in this pathway rather than the number of variables collected.

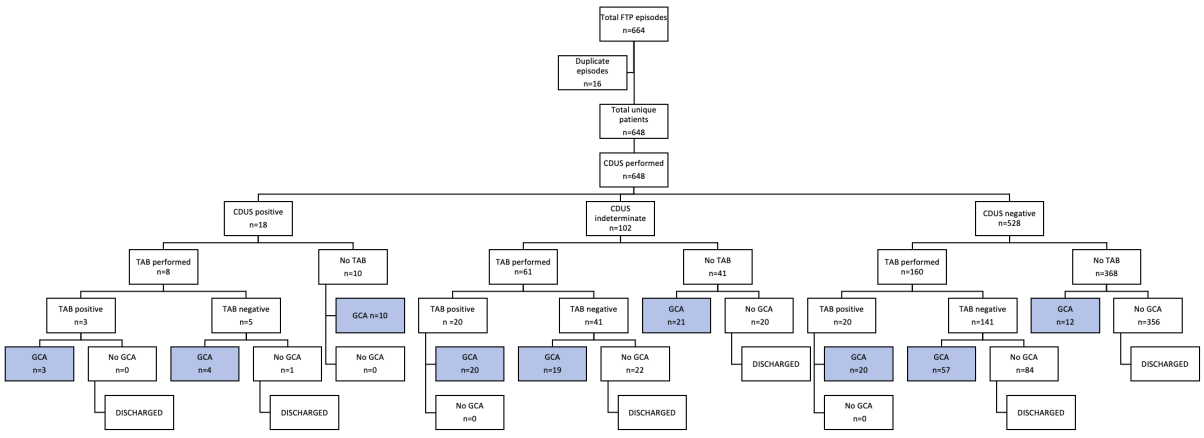
Of those referred through the fast-track pathway, 511/648 (78.8%) patients were managed by Rheumatology, 39/648 (6.0%) by Ophthalmology, 45/648 (6.9%) by a combination of both and 53/648 (8.2%) by other teams, which included General Medicine or Neurology.

Colour Doppler Ultrasound

All patients in the fast-track pathway had CDUS performed. Out of 648 CDUS scans, 18 (2.8%) were reported as positive with the halo sign, 102/648 (15.7%) had abnormal vessel wall thickening noted and were thus labelled as indeterminate, and 528/648 (81.5%) were negative. Axillary involvement was noted with vessel wall thickening (no axillary halos noted) in 52/648 (8.0%) of patients. A final diagnosis of Giant Cell Arteritis was made in 166/648 (25.6%) of patients.

Figure 2 illustrates the flow of patients through the pathway, outlining investigations performed. It shows how patients exited the pathways if they did not have Giant Cell Arteritis.

Figure 2. Flow chart of patients through the Waikato Giant Cell Arteritis fast-track pathway



NB: FTP = fast-track pathway; CDUS = colour doppler ultrasound; TAB = temporal artery biopsy; GCA = giant cell arteritis

For patients with a halo sign (all of which were in the temporal artery), 17/18 (94.4%) had a final diagnosis of Giant Cell Arteritis. There was one patient with a halo sign on CDUS but clinical review assessed them as not having Giant Cell Arteritis. Out of the 102 patients with an indeterminate CDUS, 60/102 (58.8%) had a final diagnosis of Giant Cell Arteritis. Out of

those with a negative CDUS, 89/528 (16.8%) had a final diagnosis of Giant Cell Arteritis. The sensitivity and specificity of CDUS compared to different reference standards are summarised in table 2.

Table 2. Sensitivity and Specificity of colour doppler ultrasound compared to different reference standards.

Reference	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
	% (95% confidence interval)			
Clinical diagnosis	10.3 (6.3 to 15.5)	99.8 (99.1 to 100)	94.4 (77.7 to 99.7)	76.5 (73.1 to 79.7)
Temporal artery biopsy	7.1 (1.8 to 17.5)	97.3 (94.3 to 99.0)	37.5 (11.0 to 71.0)	82.4 (77.0 to 87.0)
ACR 2022 criteria $\geq$ 6	4.7 (2.8 to 7.1)	99.6 (98.4 to 100.0)	94.4 (77.7 to 99.7)	43.9 (40.0 to 47.8)

PPV = positive predictive value, NPV = negative predictive value, TAB = temporal artery biopsy, ACR = American College of Rheumatology

Non-specific vessel wall thickening was noted in 102 patients (i.e., indeterminate scans) and in 21/102 (20.5%) of these patients, this was supportive enough for a final diagnosis of Giant Cell Arteritis without a temporal artery biopsy needing to be performed. A further 61/102 (59.8%) patients required a temporal artery biopsy of which 20/61 (32.8%) were positive and thus labelled as Giant Cell Arteritis, 41/61 (67.2%) were negative and of these, 19/41 (46.3%) were diagnosed with Giant Cell Arteritis. Thus, in total, 60/102 (58.8%) of indeterminate CDUS were associated with a diagnosis of Giant Cell Arteritis.

The sensitivity of a non-negative CDUS (i.e., either halo sign present or vessel wall thickening) was 46.7% (95% CI: 39.1 to 54.3%) and specificity was 91.1% (95% CI: 88.3 to 93.4%). The positive predictive value was 64.2% (95% CI: 55.4 to 72.4%) and negative predictive value was 83.3% (95% CI: 80.0 to 86.3%).

Corticosteroids were started in 73.5% of patients. The mean (SD) was 13.8 (55.6) days of corticosteroids prior to CDUS and the median (IQR) was 1 (1 to 4) day. For patients with a final diagnosis of Giant Cell Arteritis, those with a positive CDUS had a mean (SD) duration pre-ultrasound of 0.7 (SD 1.1) days and a median (IQR) of 0 (0 to 1.3) days. This compared to a mean (SD) of 14.2 (56.2) days and median (IQR) of 1 (0 to 4) days in patients with a negative CDUS (p=0.007). When patients who were already on corticosteroids for polymyalgia rheumatica were excluded from analysis, the mean and median did not change for the positive CDUS group but the mean (SD) 3.1 (13.1) and median (IQR) 1 (o to 3) days for the negative CDUS group with statistical difference between the two groups (p=0.022).

Temporal Artery Biopsy

Temporal artery biopsy was performed in 229/648 patients and was positive in 42/229 (18.3%) patients. The mean (SD) size of biopsy was 16.0 (9.8) mm. The British Society of Rheumatology guidelines recommend a biopsy length of at least 10mm [18]. In this cohort, 48/229 patients (21.1%) had a temporal artery biopsy length less than 10mm, with 5/48 (10.4%) of these biopsies being positive.

Time to temporal artery biopsy was mean (SD) 14.5 (20.6) days with a median (IQR) of 10 (IQR 5 to 17) days. Duration of corticosteroids prior to temporal artery biospy was mean (SD) 25.1 (46.1) days with a median (IQR) of 12 (4 to 25.5) days. The sensitivity and specificity of temporal artery biopsy with clinical diagnosis as a reference standard were 34.4% and 100% respectively.

Temporal artery biopsy was avoided in 43/648 (6.6%) of patients with Giant Cell Arteritis after having a CDUS performed.

Prior to the pathway being established (i.e., 2011 to 2013), the mean annual incidence of all TAB requests was 28.1 (95% CI: 23.0 to 33.3) per 100,000 people over 50 years. This reduced to 21.5 (95% CI: 19.1 to 23.8) per 100,000 people over 50 years. Given the slight overlap of confidence intervals, this was not statistically significant but was clearly trending downwards in conjunction with the introduction of the fast-track pathway.

Patients Discharged from the Pathway

Focusing on patients exiting the pathway, there were 376/648 patients (58.0%) who were discharged after a CDUS who did not have a final diagnosis of Giant Cell Arteritis. These patients had a mean (SD) of 15.6 (66.9) days and a median (IQR) of 1 (0 to 4) days of corticosteroids. Patients without Giant Cell Arteritis but who had a temporal artery biopsy and a CDUS performed had a mean (SD) duration of corticosteroids of 23.7 (SD 36.6) and a median of 12 (3 to 27) days. This is significantly longer than those patients who were discharged after only a CDUS ($p<0.001$). When patients who were previously on corticosteroids for polymyalgia rheumatica were excluded, the mean (SD) and median (IQR) for the CDUS only group was 3.0 (16.0) days and 0 (0 to 2) days respectively. In the CDUS and temporal artery biopsy group, this was a mean (SD) 12.4 (12.) and median ((2 to 19) days, remaining a statistically significant difference ($p<0.001$).

Covid-19 Pandemic

Aotearoa New Zealand had an initial lockdown period due to the covid-19 pandemic in March to May 2020 and a subsequent lockdown in August to September 2021 when there was community transmission. During these time periods, the service remained in place where patients and physicians had access to colour doppler ultrasound and temporal artery biopsy.

Reviews occurred via telephone consultation unless the patient was unwell, in which case a face-to-face review was organised.

Discussion

This real-world study of the Waikato Giant Cell Arteritis fast-track pathway is the largest cohort published to date alongside the study by Pinnell and colleagues [19] who had 620 patients. The benefit of a fast-track pathway for Giant Cell Arteritis is clear with significant numbers of patients avoiding temporal artery biopsy, an invasive and costly investigation for both patient and healthcare systems [1]. This was evident for low-risk patients without Giant Cell Arteritis who had a non-positive CDUS result. This could also be appreciated by the down trending rate of temporal artery biopsy requests with implementation of the pathway. The reduction in exposure to corticosteroids by only having CDUS to investigate Giant Cell Arteritis rather than needing a temporal artery biopsy was significant. This would likely translate to reduced corticosteroid toxicity for patients.

We note that our data is reflective of temporal artery biopsy access in Aotearoa New Zealand but may not be as significant a finding in other centres with rapid access to temporal artery biopsy. Rheumatology patients with suspected Giant Cell Arteritis are referred to vascular surgery, an under-resourced service where waiting times to temporal artery biopsy are often out of the optimal window. For a portion of patients with a higher probability of Giant Cell Arteritis, the positive or indeterminate CDUS result was supportive enough to commit to the diagnosis and avoid the need for biopsy.

This study helps assess the performance of colour doppler ultrasound in a real-world setting where due to practical and safety reasons, corticosteroids are commenced at the time of referral. The sensitivity in our study is significantly lower than that reported in numerous meta-analyses. Table 3 provides a comparison of our data to other meta-analyses. Corticosteroid use appears to significantly decrease the chance of a positive colour doppler ultrasound and may be part of the reason for our lower sensitivity. Pinnell et al also performed a real-world study which had a lower sensitivity for colour doppler ultrasound. They demonstrated the impact that corticosteroids had on detecting a positive CDUS and an increase in sensitivity when ultrasound was performed without corticosteroids[19].

Table 3. Meta-analyses on the performance of colour doppler ultrasound in Giant Cell Arteritis.

Study		Sensitivity (%)	Specificity (%)
Clinical diagnosis as reference standard			
Duftner 2018 [3]		77	96
Sebastian 2021 [4]		67	95
Moreel 2023 [5]		80	95
	(including large vessels)	95	96

Nakajima 2023 [6]		76	93
	(including axillary arteries)	86	95
Temporal artery biopsy as reference standard			
Karassa 2005 [7]		69	82
Duftner 2018 [3]		70	84
Rinagel 2019 [8]		68	81
Sebastian 2021 [4]		63	90
ACR Criteria 1990 as reference standard			
Karassa 2005 [7]		55	94
Arida 2010 [9]		68	91
Current Study			
	Clinical diagnosis	10.3	99.8
	Temporal artery biopsy	7.1	97.3
	ACR 2022 Criteria	1.3	90.0

ACR = American College of Rheumatology;

Corticosteroids appear to contribute to the disappearance of the halo sign [1, 20-22]. Hauenstein and colleagues [20] noted that if colour doppler ultrasound was performed on the first day of corticosteroid treatment, the sensitivity of the ultrasound was 88%. It dropped to 50% after 2-4 days of corticosteroids and 50% if patients had more than 4 days of corticosteroids.

Whilst the number of positive colour doppler ultrasounds is small, there is a larger number with increased thickening of the blood vessel wall. It remains unknown if any of these would have manifested a halo sign if corticosteroids had been withheld until after the ultrasound was performed. In the development of our fast-track pathway in Waikato, urgent corticosteroid treatment is mandatory to avoid consequences. Our protocol design and the restraints on our healthcare system cannot always guarantee a same-day CDUS.

Despite this emerging association, corticosteroid exposure may not entirely explain the discrepancy in the number of positive colour doppler ultrasounds in our study compared to others, and the reasons are probably multi-factorial. There may be a larger number of low-risk patients entering the pathway which reduces the number of true Giant Cell Arteritis cases, which is reflected by 37.6% of patients being categorised as very low or low risk through the prediction score. Of note, Sebastian et al [4] and Melville et al [2] had similar risk profiles in their study and yet had 37.6% and 30.2% positive scans respectively. The total number of cases of clinically diagnosed Giant Cell Arteritis in our study was 19.7%, which is smaller compared to Sebastian et al's and Melville et al's studies of 25% and 34.1% respectively [2, 4].

Technical factors including ultrasound machines and probes may play a role given that Aotearoa New Zealand has a resource-limited healthcare system with ultrasonographers using older, less advanced equipment at the start of the time period. Our ultrasonographers are experienced in vascular ultrasound, however, it remains unclear as to how this compares

to experts internationally-trained specifically in the features of Giant Cell Arteritis on ultrasound. We are currently undertaking a retrospective audit on the ultrasounds to look for any features of Giant Cell Arteritis that had not been reported in the final report and will use this to further improve the fast-track pathway.

The majority of patients in this cohort are referred to Rheumatology with smaller proportions of referrals to Ophthalmology. Other studies have not noted this discrepancy between specialties [19]. Our fast-track pathway protocol recommends that patients with any visual symptoms are referred to Ophthalmology. Rheumatology had 25% of their patients reporting any visual symptoms suggesting some of their patients should be seen by Ophthalmology instead.

As we reflect on the implementation of this fast-track pathway in Waikato, we can visualise potential improvements. The fact that 3.8% of patients were under 50 years raises a question that many low-risk patients were entering the pathway, perhaps inappropriately. There is a significant proportion (189/648 (37.6%)) of patients who are low or very low risk entering the pathway, though 12/189 (6.3%) of these had a final diagnosis of Giant Cell Arteritis. It is difficult to know if this reflects the weaknesses of prediction scores for Giant Cell Arteritis or the entry of too many low-risk patients to the pathway. As a real-world study, physicians have varying levels of confidence in excluding Giant Cell Arteritis in low-risk patients and this is reflected in our data. We must note that when the pathway was developed in 2013, in order to validate the safety, efficacy and accuracy of the pathway for the investigation of Giant Cell Arteritis, all patients regardless of risk needed to go through the pathway. The CDUS was a new test to the department and caution was exercised. Given the pathway is now well-established, review of entry criteria and exploring other prediction tools would be appropriate to reduce unnecessary patients going through. Clearly, ultrasound access has improved but access to temporal artery biopsy is delayed and more focus could be on improving this aspect of the pathway.

We acknowledge other limitations to this study. It is a retrospective study and there was missing data due to inadequate documentation. We have not included patients from the private health community in Aotearoa New Zealand. However, the private sector does not have the same rapid access to colour doppler ultrasound as this pathway does, thus most patients would have entered the public health system to access the pathway. Lastly, we acknowledge that there is no conventional pathway data to provide a true reflection of the benefit that this pathway has had on the Waikato community.

Conclusion

Fast-track pathways using temporal artery colour doppler ultrasound in the investigation of giant cell arteritis are beneficial to patients and our healthcare systems. There is a reduction

in the number of temporal artery biopsies required and subsequent reduction in exposure to corticosteroids in patients without GCA. Corticosteroid exposure, whilst often mandatory in preventing serious complications, appears to reduce the sensitivity of colour doppler ultrasound and remains an issue to consider when designing a fast-track pathway. Reflection around entry criteria to such pathway is also crucial.

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The first author has been employed part-time by the Waikato Hospital, Te Whatu Ora, for 12 months in a research position to carry out this research project amongst others as well as perform a clinical-role. There is no other specific funding towards the project.

Disclosures and conflicts of interest

There are no disclosures.

Ethics Statement

National ethics approval was granted by HDEC (Reference: 2023 EXP 15448) and there was a local assessment through the Waikato Hospital who also approved the project (RD023025) which included review by Te Puna Oranga Māori Consultation Research Review Committee.

Acknowledgements

We acknowledge Judith Jade for her contribution in the establishment of this pathway.

Appendix

Table 4. Duplicate episodes in the Fast-Track Pathway with reasons for subsequent episode.

Number of patients (n=16)	**Reason for Duplicate Episode**		
Patients n= 3	Repeat GCA-like symptoms with negative tests and no clinical diagnosis of GCA.		
Patients n=3	Repeat investigation to look for objective evidence in patients with a diagnosis of GCA. 1 of these had a subsequent positive CDUS after previous negative CDUS (difference between scans was 918 days).		
Patients n= 7	Repeat testing to look for recurrence of GCA in patients who already had a diagnosis of GCA.		
Possible missed diagnosis n =3	See descriptions below.		
	1st episode	**2nd episode**	**Final outcome**
Patient 1	Negative CDUS No GCA	380 days later. Negative CDUS + negative TAB.	GCA after 2nd episode.
Patient 2	Headache, CDUS indeterminate. TAB negative. No GCA.	572 days later. Positive CDUS. No TAB done.	GCA after 2nd episode.
Patient 3	Negative CDUS.	6 years later. Negative CDUS. Negative TAB.	GCA after 2nd episode.

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