

Original Article

Dan Med J 2023;70(7):A11220716

PET/CT compared with temporal artery biopsy for giant cell arteritis

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Dan Med J 2023;70(7):A11220716

ABSTRACT

INTRODUCTION. This study aims to evaluate the use of PET/CT compared with temporal artery biopsy (TAB) as a diagnostic tool in patients suspected of giant cell arteritis (GCA) and to determine the influence of glucocorticoid treatment on diagnostic performance.

METHODS. This was a retrospective cohort study; 191 patients booked for TAB during a five-year period were screened for inclusion. The study population was divided into two groups. A TAB group containing patients who completed only TAB to assess potential selection bias and a PET/CT + TAB group containing patients with TAB and PET/CT to evaluate the diagnostic performance. The clinical diagnosis of GCA was established after a follow-up period of minimum six months.

RESULTS. A total of 157 patients were included in the study: 77 patients in the TAB group and 80 patients in the PET/CT + TAB group. The result of TAB and PET/CT did not match in 15 cases. Overall, the negative agreement rate of TAB and PET/CT was 19% (95% confidence interval (CI): 11-29%). The sensitivity of PET/CT was 76% (95% CI: 63-90%) compared with the clinical diagnosis. The sensitivity of TAB was lower: 63% (95% CI: 48-78%), but not significantly different ($z = 1.26/p = 0.2$). The sensitivity of both PET/CT and TAB increased to 85% (95% CI: 72-99%) and 74% (95% CI: 58-91%) if performed within three days of glucocorticoid therapy.

CONCLUSION. This study strengthens the evidence that conventional PET/CT is a useful imaging modality in the diagnosis of the entire spectrum of GCA, including the assessment of both cranial and extra-cranial arteries.

FUNDING. None.

TRIAL REGISTRATION. Not relevant.

Giant cell arteritis (GCA) is the most common systemic large vessel vasculitis in Scandinavia with an incidence of 19-25 per 100,000 [1]. The main clinical presentations of GCA are new-onset headache, jaw-claudication, visual disturbances, musculoskeletal symptoms and high levels of inflammatory markers. However, the clinical presentation differs depending on the arteries involved [2].

Quick initiation of treatment with high-dose glucocorticoids is important to minimise the risk of ischaemic complications and permanent visual loss. However, such treatment carries a risk of side effects and complications [3], why prompt and accurate diagnosis is essential.

The diagnostic process for patients suspected of GCA is often challenging and varies depending on their clinical presentation and test options available on site. Thus, many patients undergo several different diagnostic modalities, which is costly and may cause treatment delay.

Temporal artery biopsy (TAB) has previously been considered the diagnostic gold standard for GCA. The procedure has been questioned due to its invasiveness, moderate sensitivity and the fact that the analysis takes days [4]. Furthermore, the inflammation is segmentary, and normal tissue may be extracted from an affected artery. Consequently, imaging modalities have become essential diagnostic tools.

The European League Against Rheumatism (EULAR) 2018 guidelines [5] and the Danish national guidelines [6] are similar in recommending diagnostic imaging in patients suspected of GCA. Both guidelines recommend ultrasound (US) as the first-line diagnostic test for all patients with symptoms of GCA because of its reliability [7]. But the guidelines differ as EULAR recommends ¹⁸F-fluorodeoxyglucose (FDG)-PET/CT for assessment of extra-cranial arteries only [8], whereas the Danish guideline recommends PET/CT as a second-line test or if US is not available for GCA regardless of the affected arteries. PET/CT has already been established as an important tool for assessing extra-cranial vessels [9-12], but recent studies have suggested that PET/CT also reliably assesses cranial arteries [13-16]. Furthermore, a study by Nielsen et al. 2020 [17] showed similar diagnostic performances of PET/CT and US in the diagnosis of GCA and assessment of cranial arteries.

This is a retrospective cohort study consisting of patients suspected of GCA who underwent both TAB and PET/CT. The primary aim was to assess the diagnostic performance of PET/CT compared with TAB for diagnosis of GCA and to determine the influence of glucocorticoid treatment on diagnostic performance. The secondary aim was to evaluate how accurate PET/CT assesses vasculitis activity for both large vessels and cranial arteries.

METHODS

This was a retrospective cohort study conducted at Gødstrup Hospital, DK-7400 Herning. All patients booked for TAB at the Ear- nose- and throat (ENT) Department between 1 January 2017 and 31 December 2021 were screened for inclusion. The study population was divided into two groups. One group contained patients who completed only TAB (TAB group), and one group contained patients who completed both TAB and PET/CT (PET/CT + TAB group). The PET/CT + TAB group was used to compare the diagnostic performances of the two procedures with those of the reference diagnosis described below. The TAB group was used solely as reference group to assess potential selection bias and thereby the validity of the results in the PET/CT + TAB group.

The inclusion criteria were age \geq 50 years with a completed TAB. Patients were excluded if data were unavailable in the electronic patient journal (EPJ) and if the patient had not been followed for at least six months. Based on EPJ, data on clinical history, biochemistry, imaging and pathology were registered. Signs and symptoms were retrieved from physician reports prior to PET/CT and TAB.

To evaluate the influence of glucocorticoids, the duration of treatment before TAB or PET/CT was converted into categorical data (> 3 and ≤ 3 days) [18].

The study was approved by the institutional review board at Gødstrup Hospital.

Reference diagnosis

In this study, the diagnosis of GCA was established by an experienced rheumatologist during a minimum six-month follow-up period, and the results were acquired from physician reports in the EPJ. The diagnosis was based on the presence of clinical symptoms, response to treatment and biochemical, imaging and histological results. In case of an uncertain diagnosis, the patient was included in the non-GCA group.

Assessment of PET/CT

Whole-body PET/CT was performed using one of two Siemens Biograph mCT PET/CT scanners at the department of Nuclear Medicine at Gødstrup Hospital. The software programme used for visual assessment was syngo.via

(Siemens).

Data from PET/CT were assessed by a nuclear medicine specialist in accordance with national guidelines [19, 20]. The diagnosis of GCA was based on the presence of FDG uptake in the arterial vascular wall. No specific cut-off level for pathological FDG uptake was established. However, the scan was considered positive for GCA in larger extra-cranial vessels if FDG uptake was moderate or higher (\geq liver activity). The scan was considered positive in cranial vessels in case of slightly increased FDG uptake (\geq blood pool activity). Overall, PET/CT was considered positive for GCA if any artery segment was positive. The assessment of PET/CT was made before the final diagnosis and with access to all patient data. The results were obtained from the medical record. No changes occurred in the use of scanners, software, procedures or assessment of the PET/CT during the five-year inclusion period.

Assessment of temporal artery biopsy

All TABs were performed at the ENT-Department at Gødstrup Hospital, and the tissue samples were evaluated by an experienced pathologist. The TABs were considered positive in the presence of inflammatory infiltrate in any vascular wall layer. The pathologists had access to all patient data, and results were obtained from the original pathology report.

Statistical analysis

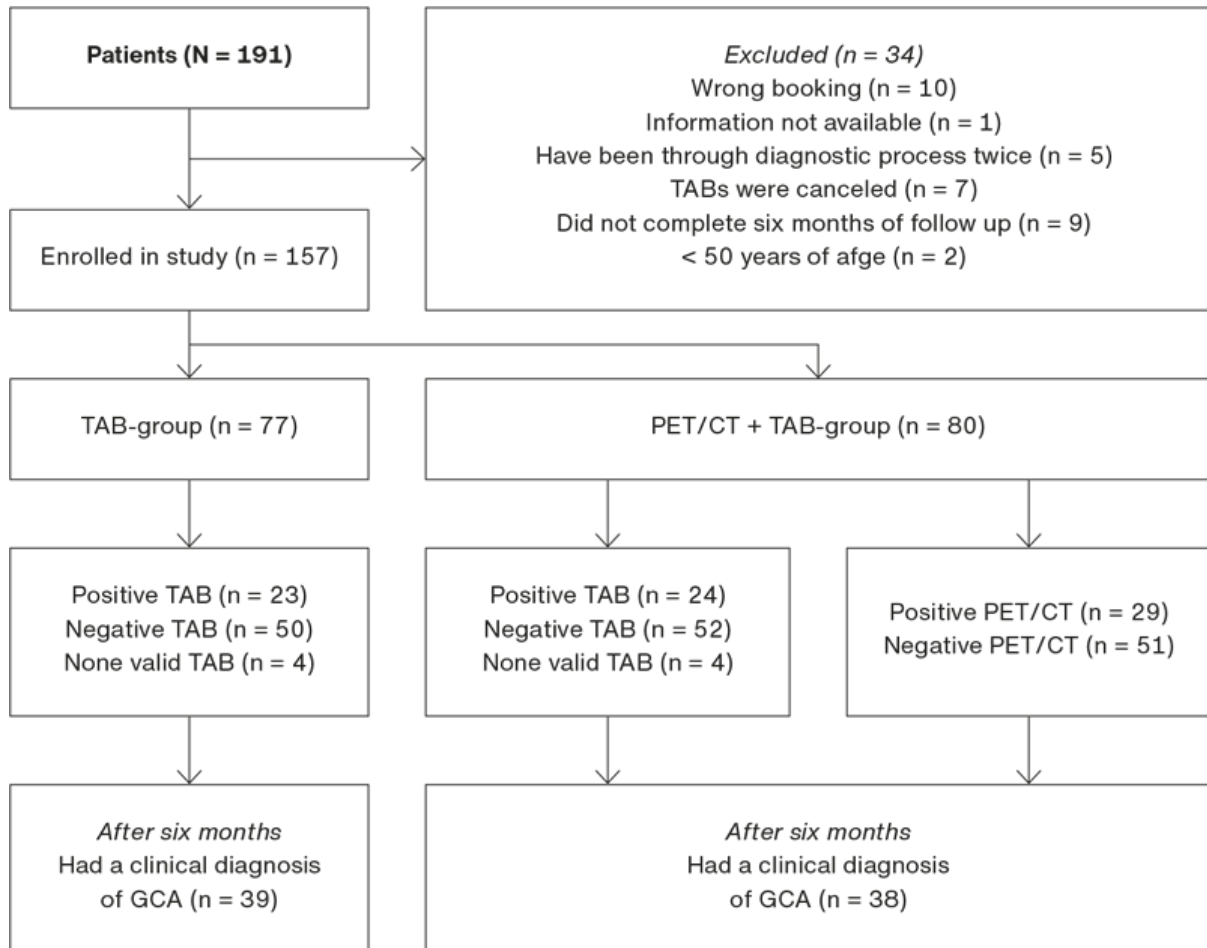
The statistical analysis was performed using Microsoft Excel. Continuous variables are presented as mean with 95% confidence intervals (CI), and categorical variables are presented as total numbers and percentages. A z-test was used to evaluate the differences between two groups. In case of more than two groups, the chi-squared test was used for categorical data and one-way ANOVA for continuous data. A level of 0.05 was considered statistically significant.

Trial registration: not relevant.

RESULTS

In total, 191 patients were screened: 157 were included in the study and 34 (17.8%) were excluded due to the reasons presented in **Figure 1**.

FIGURE 1 Patient flow diagram.



GCA = giant cell arteritis; TAB = temporal artery biopsy.

The 157 patients enrolled in the study were divided into two groups (Figure 1). Baseline characteristics of all patients are listed in **Table 1**. The 80 patients in the PET/CT + TAB group were used to evaluate the diagnostic performance of TAB and PET/CT (**Table 2**). The sensitivity of PET/CT was 76% (95% CI: 63-90%), the sensitivity of TAB was 63% (95% CI: 48-78%) and the corresponding negative predictive values were 82% (95% CI: 69-92%) and 75% (95% CI: 61-86%), respectively. However, the differences were statistically non-significant ($z = 1.26/p = 0.2$). The sensitivity of both PET/CT and TAB increased to 85% (95% CI: 72-99%) and 74% (95% CI: 58-91%) if the procedures were performed within three days of glucocorticoid therapy and decreased to 55% (25-84%) and 36% (8-65%) if performed after three days (**Table 2**). The impact of glucocorticoid treatment on sensitivity was statistically significant for TAB ($z = 2.25/p = 0.025$) and close to significant for PET/CT ($z = 1.86/p = 0.063$) in regard to the duration of glucocorticoids (> 3 and ≤ 3 days). Overall, the negative agreement rate of TAB and PET/CT was 19% (95% CI: 11-29%) and the positive agreement rate was 81% (95% CI: 71-89%).

TABLE 1 Baseline characteristics. The statistical analyses are based on comparison of all four groups: temporal artery biopsy group (giant cell arteritis and non-giant cell arteritis) and the PET group (giant cell arteritis and non-giant cell arteritis)^a.

	All patients (N _{all} = 157)		TAB-group (N _T = 77)		TAB + PET/CT-group (N _{TFC} = 80)	
	GCA (n = 77)	non-GCA (n = 80)	GCA (n = 39)	non-GCA (n = 38)	GCA (n = 38)	non-GCA (n = 42)
Female/male, n (%)	51/26 (66/34)	45/35 (56/44)	26/13 (67/33)	22/16 (58/42)	25/13 (66/34)	23/19 (55/45)
Age at inclusion, mean (95% CI), yrs	71.1 (69.4-72.8)	72.2 (70.3-74.1)	71.2 (68.6-73.8)	71.8 (69.1-74.5)	71.0 (68.6-73.4)	72.5 (69.8-75.2)
Duration of glucocorticoid treatment before TAB: ≤ 3 days/> 3 days, n (%)	51/26 (66/34)	44/36 (55/45)	24/15 (62/38)	21/17 (55/45)	27/11 (71/29)	23/19 (55/45)
Duration of glucocorticoid treatment before PET/CT: ≤ 3 days/> 3 days, n (%)	-	-	-	-	27/11 (71/29)	27/15 (64/36)
<i>Signs and symptoms</i>						
New-onset headache, n (%)	61 (79)	56 (70)	33 (85)	27 (71)	28 (74)	29 (69)
Jaw claudication, n (%) [*]	41 (53)	15 (19)	22 (56)	8 (21)	19 (50)	7 (17)
New-onset visual disturbances, n (%)	28 (36)	43 (54)	17 (44)	18 (47)	11 (29)	25 (60)
Musculoskeletal symptoms, n (%)	35 (45)	32 (40)	16 (41)	13 (34)	19 (50)	19 (45)
CRP concentration, mean (95% CI), mg/l [*]	71.4 (55.9-86.9)	43.6 (30-57.2)	53 (33.3-72.7)	40.8 (19-62.6)	90.2 (67.7-112.7)	46 (28.9-63.1)
ESR, mean (95% CI), mm/h [*]	63.5 (57.2-69.8)	40.8 (34.4-47.2)	52.4 (43.6-61.2)	40.6 (29.9-51.3)	73.2 (65.4-81)	41.1 (33.3-48.9)
<i>Comorbidities, n (%)</i>						
CNS	6 (8)	14 (18)	3 (8)	4 (11)	3 (8)	10 (24)
Cardiovascular	39 (51)	43 (54)	20 (51)	21 (55)	19 (50)	22 (52)
Pulmonary	12 (16)	10(13)	8 (21)	7 (18)	4 (11)	3 (7)
Urogenital	5 (6)	10 (13)	3 (8)	5 (13)	2 (5)	5 (12)
Gastrointestinal	6 (8)	9 (11)	5 (13)	4 (10)	1 (3)	5 (12)
Endocrinological [*]	12 (16)	25 (31)	8 (21)	16 (40)	4 (11)	9 (21)
Rheumatic	7 (9)	12 (15)	6 (15)	8 (21)	4 (11)	4 (10)
Malignancy	10 (13)	16 (20)	6 (15)	6 (16)	4 (11)	10 (24)
PMR	35 (45)	16 (20)	17 (44)	16 (42)	18 (47)	15 (36)
No significant comorbidities	21 (27)	10 (13)	9 (23)	2 (5)	12 (32)	8 (19)

CI = confidence interval; CNS = central nervous system; ESR = erythrocyte sedimentation rate; GCA = giant cell arteritis; PMR = polymyalgia rheumatica; TAB = temporal artery biopsy. ^{*} p ≤ 0.05.

a) Further statistical analysis between the individual groups resulted in the following: jaw claudication (z = 4.81/p ≤ 0.001), CRP (z = 2.65/p = 0.008) and ESR (z = 4.96/p ≤ 0.001) differed significantly between all GCA patients versus all non-GCA patients. The PET/CT + TAB group showed significantly and close-to-significantly higher levels of ESR (z = 2.09/p = 0.036) and CRP (z = 1.87/p = 0.06) than the TAB group. The GCA-positive patients in the PET/CT+TAB group had significantly higher CRP (z = 2.44/p = 0.015) and ESR (z = 3.47/p ≤ 0.001) than non-GCA patients. Furthermore, fewer GCA patients had endocrinological comorbidities (z = 2.36/p = 0.02) and more had no significant comorbidities (z = 2.36/p = 0.02) than among non-GCA patients.

TABLE 2 The diagnostic accuracy of PET/CT and temporal artery biopsy compared to the clinical diagnosis of giant cell arteritis, within the temporal artery biopsy + PET/CT-group^a.

	PET/CT			TAB		
	positive	negative	all	positive	negative	all
<i>Clinical diagnosis, total (≤ 3 days/> 3 days^b), n</i>						
Positive	29 (23/6)	9 (4/5)		24 (20/4)	14 (7/7)	
Negative	0	42 (27/15)		0	42 (23/19)	
Subtotal	29 (23/6)	51 (31/20)		24 (20/4)	56 (30/26)	
<i>All patients, mean (95% CI), %</i>						
Sensitivity			76 (63-90)			63 (48-78)
Specificity			100 (92-100)			100 (92-100)
Positive predictive value			100 (88-100)			100 (86-100)
Negative predictive value			82 (69-92)			75 (61-86)
<i>≤ 3 days of glucocorticoid treatment, mean (95% CI), %</i>						
Sensitivity			85 (72-99)			74 (58-91)
Specificity			100 (87-100)			100 (83-100)
Positive predictive value			100 (85-100)			100 (83-100)
Negative predictive value			87 (70-96)			77 (58-90)
<i>> 3 days of glucocorticoid treatment, mean (95% CI), %</i>						
Sensitivity			55 (25-84)			36 (8-65)
Specificity			100 (78-100)			100 (82-100)
Positive predictive value			100 (54-100)			100 (40-100)
Negative predictive value			75 (51-91)			73 (52-88)

CI = confidence interval; TAB = temporal artery biopsy.

a) Statistical analyses are based on comparing PET/CT and TAB.

b) Duration of glucocorticoid treatment before TAB or PET/CT.

The PET/CT + TAB group consisted of 80 patients of whom 38 had GCA and 29 of these 38 patients (76%) had a positive PET/CT. All PET/CT positive scans were evaluated for involvement of specific arteries and related to the TAB findings in Table 3.

TABLE 3 PET/CT-positive involvement of arteries.

	TAB-positive (n = 19)	TAB-negative (n = 10)	Total (N = 29)
Only cranial arteries ^a , n	8	1	9
Only large vessels ^b , n	5	6	11
Cranial and large vessels, n	6	3	9
Cranial artery involvement, mean (95% CI), %	73.7 (48.8-90.9)	40 (12.2-73.8)	62 (42.3-79.3)
Large vessel involvement ^c , mean (95% CI)*, %	57.9 (33.5-79.8)	90 (55.5-99.8)	69 (49.2-84.7)

CI = confidence interval; TAB = temporal artery biopsy.

*) $p \leq 0.05$.

a) Cranial arteries included temporal, maxillary, vertebral and occipital arteries.

b) Large vessel included aorta, carotid, subclavian, axillary and iliac arteries.

c) % of large vessel involvement was significantly higher ($z = 2.17/p = 0.3$) in TAB-negative patients than in TAB-positive patients.

Overall, 69% of positive PET/CTs showed large-vessels involvement and 62% involved cranial arteries. The TAB and PET/CT results did not match completely. Ten out of 29 patients (34%) with a positive PET/CT had a negative TAB and four of the ten patients had affected cranial arteries according to PET/CT (Table 3).

In total, nine patients had clinical GCA but a negative PET/CT; five of whom had a positive TAB. However, all five patients had TAB done prior to PET/CT with a mean duration of glucocorticoid treatment of 2.4 days (95% CI: 0.93-3.87) before TAB and 4.4 days (95% CI: 2.93-5.87) before PET/CT. The remaining four patients with negative TAB and PET/CT were diagnosed with clinical GCA based on relevant clinical presentation and high levels of erythrocyte sedimentation rate (ESR) (mean 88.7 mm/h) and c-reactive protein (CRP) (mean 165.75 mg/l).

DISCUSSION

This study evaluated the diagnostic performance of whole-body PET/CT compared with TAB in patients suspected of GCA. Our study showed a trend towards PET-CT being a better diagnostic tool than TAB for the diagnosis of GCA based on the difference in sensitivity (76% versus 63%) and the negative predictive value (82% versus 75%), though none of these findings were statistically significant. The diagnostic performance of both PET/CT and TAB increased if performed within three days of glucocorticoid treatment (85% and 74%).

In the present study, both PET/CT and TAB were used to establish the diagnosis of GCA, consequently leading to a specificity and a positive predictive value of 100% and potentially increasing the sensitivity. Therefore, the specificity and the positive predictive value in this study are irrelevant. On the other hand, using TAB and PET/CT to establish the diagnosis is the clinical practice and ultimately results in a more certain reference diagnosis. In line with the study by Nielsen et al. 2018 [18], this study found a significant and close to significant increase in the sensitivity of TAB and PET/CT when performed within three days of glucocorticoid treatment, emphasising the importance of performing the PET/CT within three days to maintain a high sensitivity. Nine patients in this study had a false negative PET/CT, five of whom had a positive TAB. Of the five patients, only two had PET/CT performed on the third day of glucocorticoid treatment. The rest had longer treatment duration

before scanning. Potentially, glucocorticoid treatment may be a source of false-negative PET/CT results.

The study showed a significantly higher percentage of large-vessel involvement in TAB-negative compared with TAB-positive patients as illustrated in Table 3. This is unsurprising as PET/CT is not limited to the temporal artery, possibly explaining the higher sensitivity of PET/CT compared with TAB. Furthermore, PET/CT equally assess involvement of cranial arteries and large vessels (62% versus 69%) in GCA, which is in line with Nielsen et al. 2019 [13] and Nienhuis et al. 2020 [14].

The strengths of this study are, firstly, that all PET/CTs and all TABs were performed at one site, and no changes in procedures were made during the inclusion period. Secondly, a reference group was included, consisting of patients undergoing only TAB. This allowed for a comparison of the two groups and an assessment of potential selection bias. Our results showed that GCA patients with higher levels of CRP and/or ESR had an increased chance of undergoing PET/CT, indicating selection. A possible explanation is that PET/CT is performed on clinical indications, and high levels of CRP and ESR are generally red flags of infection, inflammation and neoplastic diseases. PET/CT is a great diagnostic tool for differential diagnostics, consequently increasing the number of patients with high levels of CRP and ESR in the PET/CT + TAB group. Overall, patients with GCA had significantly higher levels of CRP and ESR than non-GCA patients. These facts combined may potentially indicate some selection bias which would lead to a falsely higher sensitivity in the PET/CT + TAB group. Other limitations are the small sample size of patients in the various subgroups, which affects the power of the study. The group used to compare the diagnostic performance of PET/CT and TAB consisted of 38 patients and may be the reason for the statistically non-significant difference in sensitivity recorded. The retrospective nature of our study is prone to bias, causing a lack of standardisation of the diagnostic procedure, quality of data and follow-up protocol. Furthermore, the nuclear medicine physicians were not blinded to patient data, and PET/CT findings were based on visual assessment alone, increasing the risk of measurement bias.

As per the guidelines, US is first priority in the diagnosis of GCA even though PET/CT have similar diagnostic performances in the assessment of both cranial and larger vessels [17]. In general, US has several advantages compared with PET/CT. It is a low-cost, non-invasive and time-saving procedure, and the results are instant. However, the findings of vascular US are limited to the arteries reachable by US and depend on the expertise of the operator performing the procedure. Not all hospitals have access to an expert trained in vascular US. US has already been compared with PET/CT [17]. However, studies investigating the diagnostic accuracy of PET/CT using US as reference are lacking. This may be a topic of interest for future studies.

Overall, TAB is most likely an unnecessary procedure and imaging diagnostic modalities should be prioritised. This study argues that PET/CT should be prioritised before TAB, especially if vascular US is unavailable. However, to achieve high sensitivity, PET/CT should be performed within three days of glucocorticoid treatment.

CONCLUSION

This study strengthens the evidence that conventional whole-body PET/CT is a useful imaging modality in the diagnosis of the entire spectrum of GCA, including the assessment of both cranial and extracranial arteries.

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Accepted 14 April 2023

Conflicts of interest Potential conflicts of interest have been declared. Disclosure forms provided by the authors are available with the article at ugeskriftet.dk/dmj

Acknowledgements We wish to thank *Thorbjørn Hubech-Graudal* for his help in describing the scanners, software, procedures and

the assessment of the FDG PET/CT during the five-year inclusion period. Furthermore, we take this opportunity to express our gratitude to *Ellen Duedahl* for sparring and proof reading.

Cite this as Dan Med J 2023;70(7):A11220716

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