Excellent suppression of physiological myocardial FDG activity in patients with cardiac sarcoidosis.

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Abstract

Introduction:

Suppression of physiological myocardial FDG activity is vital in patients undergoing PET/CT for assessment of known or suspected cardiac sarcoidosis. This study aims to evaluate the efficacy of physiological myocardial FDG suppression following a protocol change to a 24-hour high fat very low carbohydrate (HFVLC) diet and prolonged fast.

Method:

A retrospective review of patients undergoing FDG PET/CT for the evaluation of cardiac sarcoidosis was performed. Prior to June-2018, patients were prepared with a single very high fat low carbohydrate meal followed by a 12-18 hour fast (group 1). After June-2018, a protocol change was initiated with patients prepared with a HFVLC diet for 24-hours followed by a 12-18 hour fast (group 2). Focal myocardial activity was classified as positive, absent activity as negative and diffuse/focal on diffuse activity as indeterminate.

Results:

A total of 94 FDG PET/CT scans were included with 46 scans in group 1 and 48 scans in group 2. Studies were classified as positive, negative or indeterminate in 25 (54%), 7 (15%) and 14 (30%) scans in group 1 and in 13 (27%), 33 (69%) and 2 (4%) scans in group 2, respectively. In scans classified as negative, myocardial FDG activity was less than mediastinal blood pool activity in 5/7 (71%) scans in group 1 and 33/33 (100%) scans in group 2.

Conclusion:

Excellent myocardial FDG suppression can be achieved using a 24-hour HFVLC diet and prolonged fast, resulting in a very low indeterminate scan rate in patients with known or suspected cardiac sarcoidosis.

Keywords: Cardiac imaging, cardiac sarcoidosis, diet, FDG PET/CT, nuclear cardiology

Introduction

Sarcoidosis is a systemic disease which can involve the heart, although diagnosis of cardiac sarcoidosis is often challenging.(1,2) ^{18}F -fluorodeoxyglucose positron emission tomography/computed tomography (FDG PET/CT) has emerged as a useful non-invasive tool in the assessment of known or suspected cardiac sarcoidosis.(3) However, a limitation of FDG PET/CT is that physiological uptake by the myocardium may confound assessment of active disease leading to indeterminate or false positive studies. Hence, suppression of physiological myocardial FDG uptake is paramount in the assessment of cardiac sarcoidosis.

The optimal approach for achieving physiological myocardial FDG suppression remains controversial, although it is becoming increasingly accepted that there is utility in administering a high fat, low carbohydrate diet prior to the scan.(4,5) Many protocols have been proposed including a variety of dietary regimens, fasting times of various lengths and intravenous heparin administration.(6,7,8,9,10,11,12,13,14,15) The Society of Nuclear Medicine and Molecular Imaging (SNMMI) and American Society of Nuclear Cardiology (ASNC) joint statement recommends at least two high fat (> 35 g), low carbohydrate (< 3 g) meals the day before the study with a subsequent fast of 4-12 hours prior to the scan or a fast of greater than 18 hours, if dietary modification is not able to be achieved.(16) In contrast, the Japanese Society of Nuclear Cardiology recommends a low carbohydrate meal the night before the scan followed by a fasting time of 12-18 hours.(17) Given the lack of an accepted standard and variability in international guidelines, further evidence is needed to clarify the optimal preparation method.

At our institution, prior to June 2018, patients with known or suspected cardiac sarcoidosis were prepared with a single very high fat low carbohydrate meal followed by a 12-18 hour fast. After June 2018, due to clinical concern over a relatively high proportion of scans exhibiting a degree of background diffuse myocardial FDG activity, a protocol change was initiated with patients prepared with a high fat very low carbohydrate (HFVLC) diet for 24-hours prior to the scan, followed by a 12-18 hour fast.

The aim of this study was to evaluate the efficacy of physiological myocardial FDG suppression following the protocol change to our post-June 2018, 24-hour HFVLC diet and prolonged fast of 12-18 hours.

Methods

Data collection

A retrospective review of FDG PET/CT scans was performed in patients referred to our department for the evaluation of known or suspected cardiac sarcoidosis between November 2015 and November 2019. The study was approved by our institutional hospital ethics committee. Clinical demographic data including patient age, gender and weight was obtained for each scan. FDG uptake time and pre-test blood glucose levels were also recorded (Table 1).

Dietary preparation

Before June 2018, patients were prepared with a single very high fat low carbohydrate meal followed by a 12-18 hour fast (group 1). From June 2018, the preparation was changed to a HFVLC diet for 24-hours prior to the scan followed by a 12-18 hour fast (group 2). The HFVLC diet was formulated in conjunction with advice from our hospital dietitian with each meal consisting of < 3 g of carbohydrate and 20-35 g of fat. Details of allowed and prohibited foods as they were presented to patients are shown in Table 2. Patients were instructed to consume three HFVLC meals and a suggested meal plan was provided (Table 3). In addition, patients were also advised that any snacks and drinks must also be only from the allowed food list. The diet was strictly enforced and patients were required to keep a food diary. Patients were also instructed to avoid exercise 24 hours prior to the scan. Before the scan was performed, the food diary was reviewed and patients were rebooked if there was non-compliance with the diet. Patients with diabetes were discussed with the endocrinology service on an individual basis prior to commencing dietary preparation to minimize the risk of potential hypoglycaemic episodes.

Imaging

FDG PET/CT scanning was performed on a GE Discovery 710 PET/CT system. Images were obtained from the skull base to the proximal thighs following administration of 4 MBq/kg of FDG up to a maximum of 370 MBq. CT scans were performed at 100-140 kVp depending on patient weight, using auto-tube modulation and a slice thickness of 3.75 mm. In addition, all patients underwent myocardial perfusion assessment with ^{99m}Tc -sestamibi scanning using a GE NM/CT Discovery 690 SPECT/CT system.

Image interpretation

Myocardial FDG uptake on each scan was independently evaluated qualitatively by two experienced nuclear medicine physicians, blinded to clinical and other test data. FDG activity within the myocardium was classified as focal, focal on diffuse, diffuse or none, based on previous recommendations from the Japanese Society of Nuclear Cardiology (JSNC) with examples of these scan patterns displayed in Figure 1. (17,18) Disagreement was resolved with consensus opinion.

Studies were considered positive if they exhibited focal FDG activity within the myocardium, indeterminate if there was either focal on diffuse or diffuse FDG activity within the myocardium, or negative if there was no FDG activity within the myocardium. No FDG activity in the myocardium was defined as activity equal to or less than that of mediastinal blood pool. For studies considered positive or negative, a qualitative assessment was performed as to whether the level of FDG activity in non-inflamed myocardium was less than mediastinal blood pool. For scans classified as positive, ^{99m}Tc -sestamibi SPECT/CT perfusion scans were assessed to ensure that myocardium with no FDG activity represented viable myocardium and not fibrosis. For scans considered positive, the SUVmax of the most active cardiac lesion as well as the SUVmean of mediastinal blood pool activity was obtained with results outlined in Table 1.

Patient follow-up

Final consensus clinical diagnosis was determined by treating physicians and was identified using data from the electronic medical record, incorporating clinical features and other investigations such as cardiac MR and histology.

Statistics

Interobserver agreement was measured using a Cohen's Kappa statistic. Differences in indeterminate scan rate between group 1 and 2 were calculated and tested for statistical significance using the Fisher's exact test. $P < 0.05$ was considered statistically significant. Statistical analyses were performed using SAS software version 9.4.

Results

A total of 94 FDG PET/CT scans were performed in 67 patients for known or suspected cardiac sarcoidosis over the study period. There were 46 scans in group 1 and 48 scans in group 2. In total, 67 of these scans were for suspected disease while 27 were for follow-up of known cardiac sarcoidosis (13 in group 1 and 14 in group 2).

Classification of myocardial FDG patterns is outlined in Table 4. There was almost perfect interobserver agreement between the two reviewers (Cohen's Kappa statistic = 0.87). Scans were classified as positive, negative or indeterminate in 25 (54%), 7 (15%) and 14 (30%) scans in group 1 and in 13 (27%), 33 (69%) and 2 (4%) scans in group 2, respectively. There was a statistically significant reduction in the number of indeterminate scans in group 2 with respect to group 1 ($p = 0.0008$).

In scans classified as negative, myocardial activity was less than mediastinal blood pool activity in 5/7 (71%) scans in group 1 and 33/33 (100%) scans in group 2. In scans classified as positive, FDG activity in non-inflamed myocardium was less than mediastinal blood pool activity in 13/25 (52%) of scans in group 1 and in 11/13 (85%)

scans in group 2. All patients classified as positive had normal perfusion in the areas of non-inflamed myocardium on perfusion SPECT/CT scanning.

Clinical follow-up revealed that of the scans classified as positive, active cardiac sarcoidosis was diagnosed by clinical consensus in 19/25 (76%) scans in group 1 and in 11/13 (85%) scans in group 2. For scans classified as indeterminate, active cardiac sarcoidosis was diagnosed in 9/14 (64%) scans in group 1 and in 2/2 (100%) scans in group 2. Of the 12 focal on diffuse scans in group 1, 8 (67%) scans were diagnosed with active cardiac sarcoidosis.

Discussion

Our study shows that a strictly enforced 24-hour HFVLC diet and prolonged fast results in a very low indeterminate FDG PET/CT scan rate in the assessment of patients with known or suspected cardiac sarcoidosis. High rates of physiological myocardial FDG suppression can be achieved with this protocol, evident by myocardial FDG activity being lower than mediastinal blood pool activity in all scans classified as negative and within the areas of non-inflamed myocardium in the vast majority of scans classified as positive in patients in group 2.

Myocardial cells use a variety of metabolic substrates including glucose and fatty acids. Under fasting conditions, fatty acids are preferentially used over glucose although this process can be extremely variable. One study showed that 38% of patients still exhibit physiological myocardial FDG uptake even after an 18 hour fast. (15) Given that prolonged fasting alone is sometimes insufficient to suppress physiological myocardial FDG uptake, a combined approach of prolonged fasting and a carbohydrate restricted diet is generally recommended for patients undergoing FDG PET for cardiac sarcoidosis imaging as stated in a recent update by the Japanese Society of Nuclear Cardiology. (17) Our results support this approach, since despite both our study groups being prepared with a prolonged fast, a higher number of indeterminate results were observed in group 1. Whether a prolonged fast is required when patients are adequately prepared with a HFVLC diet remains an open question, particularly given that encouraging rates of

suppression have recently been reported from other institutions using shorter fasting protocols, even as low as 2 hours. (4,5) The use of intravenous heparin prior to FDG administration has also been proposed but its utility remains unclear and our results suggest this additional preparation method may not be necessary, potentially avoiding the associated risks of bleeding and heparin induced thrombocytopenia..(16,17) Alternative PET imaging approaches using somatostatin receptor binding radiotracers have also been reported and could potentially obviate the need for dietary preparation altogether. (3, 19, 20) However, these PET radiotracers require further study and are not as readily available as FDG.

Given the major challenges involved in diagnosing cardiac sarcoidosis, FDG PET/CT imaging is emerging as an important tool for both initial assessment of myocardial inflammation and in treatment monitoring. (21) Consistent interpretation criteria are essential to ensure confident reporting and minimization of false positive results given the serious treatment implications. Classification of myocardial FDG uptake into none, diffuse, focal and focal on diffuse patterns is an accepted practice standard and our results confirm this classification has almost perfect interobserver agreement within our institution. The interobserver agreement between institutions, however, may not be as high given that the interpretation of the focal on diffuse pattern appears to significantly vary between groups. (4,5,17,18,22) While it has been recommended to consider the focal on diffuse pattern positive for sarcoidosis inflammation, for the purposes of this study we considered this pattern indeterminate, in keeping with the opinions of Lu et al. given that a background of diffuse activity suggests at least a degree of inadequate physiologic myocardial FDG suppression. This approach is potentially supported by our clinical data where 29% of all scans displaying focal on diffuse patterns were clinically deemed not to have cardiac sarcoidosis. It is noted that had we considered the focal on diffuse pattern to be positive for sarcoidosis, we would have also achieved a low indeterminate scan rate in group 1 and no indeterminate scans in group 2. However, classifying these scans as positive may not be an optimal clinical approach given that 33% of group 1 scans with focal on diffuse patterns were considered not to have active cardiac sarcoidosis by clinical consensus. The difficulties in categorizing the focal on diffuse pattern have also been highlighted by other authors and have been expanded upon in the recently updated

recommendations by the Japanese Society of Nuclear Cardiology. These recommend this pattern be overall classified as focal on a background of either physiologic or heart failure related diffuse activity, cognizant that other causes of cardiomyopathy may also trigger localized FDG uptake. (4,17)

Limitations of our study include its retrospective design and possible referral bias, which could limit generalization of our results. Nevertheless, we believe the high rate and level of physiologic myocardial FDG suppression achieved with our strictly enforced HFVLC diet combined with a prolonged fasting protocol could potentially be reproduced by other institutions and in different study populations. While our study was not designed to assess the accuracy of FDG PET/CT in the diagnosis of active cardiac sarcoidosis, our results suggest that this preparation method provides excellent suppression of physiologic myocardial FDG activity which will significantly improve diagnostic accuracy and possibly also translate to improved accuracy of FDG PET/CT in the assessment of other cardiac inflammatory and infective conditions.

Conclusion

The combination of a 24-hour HFVLC diet and a prolonged fast results in excellent suppression of physiologic myocardial FDG activity. Strict enforcement of this protocol can result in a very low indeterminate FDG PET/CT scan rate in patients with known or suspected cardiac sarcoidosis.

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Figure (Title and Legend)

Title: Figure 1. Examples of scans classified according to Japanese Society of Nuclear Cardiology (JSNC) criteria.

Legend: Four patterns of FDG activity as classified by JSNC are displayed on attenuation corrected axial PET slices of the heart.

a) Focal, b) Focal on diffuse, c) Diffuse, d) None.

Table 1. Clinical, demographic and relevant scan information

	<u>Group 1 (n = 46). Mean (SD)</u>	<u>Group 2 (n = 48). Mean (SD)</u>
Age (years)	54.0 (12.7)	53.7 years (11.4)
Gender	29 Male, 17 Female	34 Male, 14 Female
BMI (kg/m ²)	29.3 (6.6)	30.8 (5.6)
Weight (kg)	86.1 (18.4)	92.7 (17.6)
FDG uptake time (minutes)	69.8 (10.0)	79.2 (17.6)
Pre-test blood glucose	5.8 (1.4)	5.4 (1.8)

(mmol/L)		
SUV _{max} † of cardiac lesions (g/mL)	6.8 (2.9)	6.3 (2.6)
SUV _{max} /SUV _{mean} ‡ mediastinal blood pool)	3.2 (1.2)	3.1 (1.0)

†SUV_{max}: Maximum standardised uptake value

‡SUV_{mean}: Mean standardized uptake value

Table 2. List of allowed and prohibited foods

	<u>Do not consume</u>	<u>Allowed foods</u>
Breads and cereals	Do not consume any breads, pastries, grains, wheat, rice, pasta, baked goods.	None.
Dairy products	Do not consume almost all dairy products – milk, cheese, yoghurt, custard, frûche	Some dairy foods are allowed: Butter/margarine, ricotta cheese (1/4 cup, 60g), hard cheddar cheese (4 slices, 120 g).
Fruits	Do not consume any fruits.	None.
Vegetables	Do not consume any carrot or starchy vegetables (corn, potato, sweet potato, taro, pumpkin).	Some vegetables are allowed: MUST follow strict portion guide (see the Table on the following page). Asparagus, Broccoli, Capsicum, Cauliflower, Celery, Chinese-Cabbage, Cucumber, Lettuce/Salad, Mushroom, Onion, Tomato, Zucchini.
Meats and alternatives	Do not consume sweetened/cured/grilled meats with carbohydrate additives (i.e. crumbled, hamburgers, honey glazed, marinades and sauces). No legumes, lentils, beans, cashews, peanuts, pistachios.	Some meats and alternatives are allowed: (Plain, cooked in oil or butter) Chicken, fish, beef, lamb, turkey, pork, ham/bacon, plain eggs, tofu. Tahini paste (maximum 1 tablespoon per meal). Allowed nuts include almonds, brazil nuts, macadamias, walnuts.
Condiments	Do not consume condiments as many have	Some condiments are allowed: Oil (olive, coconut)/butter/margarine, avocado (half

	hidden sugars/ carbohydrates (i.e. tomato (no other sweeteners allowed). sauce, sweet chili sauce, peanut butter, jam). Do not consume sugar or pepper.	medium – 80 g of flesh), equal sweetener 1 Teaspoon only of one of the following choices (per meal): Basil, coriander, parsley (small amount only to season food), garlic, ginger, dried chili flakes.
Sweet snacks	Do not consume any lollies, lozenges, mints, chewing gum, sweets, chips, biscuits, cakes, ice cream.	None.
Drinks	Do not consume soft drinks, cordials, alcoholic beverages, fruit juices, milk.	Drinks allowed are: Water, coffee, tea/herbal tea. No sugar or milk.

Table 3. Suggested meal plan

Non-vegetarian.	Vegetarian Alternative.
Breakfast: Eggs (x2, any style without added milk). Bacon (x2 rashers, non-sweetened) +/- serve of permitted vegetables (i.e. baby spinach, mushrooms, tomato).	Breakfast: Eggs (plain, any style without added milk). Avocado (half). 1-2 serves of permitted vegetables (i.e. mushrooms cooked in butter).
Lunch: Grilled salmon fillet 115 g + 1 tablespoon of oil.	Lunch: Nuts 30 g (plain unflavoured). Salad: with x2-3 serves of permitted vegetable portions with dressing (i.e. 1

Salad: With x2-3 permitted vegetable options (i.e. lettuce, cucumber) +/- oil as dressing.	tablespoon of tahini paste and 1 tablespoon of oil) or ¼ cup ricotta cheese.
Dinner: Meat and vegetable stir-fry: 1 tablespoon oil. Optional: x 1 fresh/dried herb/spice from permitted list (i.e. 1 teaspoon garlic) 100 g meat (beef, chicken thigh fillet/pork/lamb) Vegetables x2-3 permitted portions (i.e. cauliflower, asparagus, capsicum).	Dinner: Tofu and vegetable stir-fry: 1 tablespoon oil. Optional: x1 fresh/dried herb/spice from permitted list. 170 g tofu (hard, plain). Vegetables x2-3 of permitted portions (i.e. cauliflower, asparagus, zucchini).
Fluids: Water, Tea, Coffee only (no sugar/milk).	Fluids: Water, Tea, Coffee only (no sugar/milk).
ALLOWED VEGETABLES	
ALLOWED VEGETABLES: Single Serve Examples (= 1 SERVE) Allowed: Breakfast 1 serve, Lunch 2-3 serves, Dinner 2-3 serves. Vegetarian permitted up to 2 serves at Breakfast.	
Asparagus (approx. 60g, 4 medium spears) Broccoli (up to 200g, 2 cups) Capsicum (approx. 25g, ¼ cup) Cucumber (approx. 60g, ½ cup) Cauliflower (approx. 60g, 4 florets) Celery (approx. 50g, 3 small stalks)	Chinese cabbage (2 cups) Lettuce (iceberg /spinach, up to 100g, 3 cups) Mushroom (approx. 70g, 1 cup) Onion (approx. 20g, ¼ of medium onion) Tomato (2 cherry tomatoes, ¼ medium tomato) Zucchini (approx. 60g, ½ cup)

Table 4. Classification of FDG myocardial patterns

	Group 1 (n = 46)	Group 2 (n = 48)
Focal	25 (54%)	13 (27%)
Focal on diffuse	12 (26%)	2 (4%)
Diffuse	2 (4%)	0 (0%)
None	7 (15%)	33 (69%)

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