



Assessment of the particular demand for ^{18}F FDG/PET-CT procedures: a discussion regarding new incorporations by the SUS

Batista^a A.S.M., Silva M.S., Santana P.C.

^a *Departamento de Anatomia e Imagem, Faculdade de Medicina, Universidade Federal de Minas Gerais.*
adriananuclear@yahoo.com.br

ABSTRACT

Imaging exams considered to be of high cost have diagnostic advantages that make them relevant in the context of public health. Positron Emission Tomography associated with Computed Tomography realized with fluorodeoxyglucose (^{18}F -PET-CT) is an example of a new, high-cost, but strategic exam for the diagnosis and monitoring of diseases that can be studied through the metabolism of glucose in the body. The present work proposes a discussion about the availability of this exam by the Unified Health System, from the Portuguese Sistema Único de Saúde (SUS), trying to demonstrate the paths between the demonstration of its diagnostic value and the progressive inclusion in the list of reimbursable exams. For this purpose, data from exams carried out at the Molecular Technology Center - Faculty of Medicine/UFGM (CTMM-FM/UFGM) were used, paid in a particular way over the years 2012-2019. The results indicate a continuous search for the exam for cases associated with the diagnosis, staging and monitoring of cancer treatment, especially Lymphomas. The search for the exam with medical orders specifying a diagnostic indication not provided for by the SUS, such as colon and breast cancer, suggests the need to update the SUS reimbursement table for this diagnostic imaging modality.

Keywords: ^{18}F -PET-CT, SUS, diagnostic imaging.



1. INTRODUCTION

Positron Emission Tomography associated with Computed Tomography (PET-CT) is a molecular imaging modality that has been clinically available in Brazil since 2003, however, the technology faced some difficulties to expand and consolidate itself as a diagnostic method. In 2012 it was included in the list of procedures of the National Supplementary Health Agency (ANS), paying for tests with the following diagnostic indications: non-small cell lung cancer to characterize lesions and staging; lymphoma for staging, assessment of therapeutic response, and monitoring of relapse [1].

To obtain a functional PET image it is necessary to use a radiotracer. Currently, among those available in the Brazilian market, the most used is Fluor-18 (^{18}F). Its production takes place in a cyclotron, using water enriched with Oxygen-18 (^{18}O) bombarded with protons. After this process, ^{18}F is associated with glucose, which has the function of carrying the radionuclide to the target. Among its advantages, we can mention: relatively low half-life (109 minutes), good sensitivity and low cost compared to other radioisotopes. Another advantage is its biological and pharmacokinetic behavior similar to glucose. The only difference is that fluorodeoxyglucose is not metabolized and stored in the cell until it is excreted [2]. Due to this characteristic, ^{18}F -FDG is widely used in the diagnosis of pathologies that affect glycolytic metabolism [3].

The Unified Health System, from Portuguese *Sistema Único de Saúde* (SUS) is a world reference in terms of public management, being considered one of the largest “free” care systems; constituted by the three levels of government (Union, States and Municipalities) and the private sector through contracting of services and agreements [4]. One of the principles that guide the SUS is universality, which guarantees the system's comprehensive care for each and every individual: “Health is a right for all and a duty of the State, guaranteed through social and economic policies aimed at reducing risk disease and other health problems and universal and equal access to actions and services for the promotion, protection and recovery” – BRASIL, article 196 of the 1998 constitution.

Another no less important principle governing the SUS is equity, which aims to reduce inequalities by investing where the need is greatest, since people are not equal and have different

needs [4]. One of the ways to ensure the implementation of these principles in practice is the incorporation of technologies in the SUS, "Technological advances in recent decades have provided improvements in the quality of health of the population and a reduction in the mortality rates of a considerable number of diseases" [5].

In 2011, Law 12,401 institutionalized the Health Technology Assessment (HTA), thus allowing the establishment of necessary criteria and assisting the National Commission for the Incorporation of Technologies in the SUS (from Portuguese *Comissão Nacional de Incorporações de Tecnologias no SUS* – Conitec) in making decisions related to the inclusion, alteration or exclusion of technologies, and in the control and modification of Clinical Protocols and Therapeutic Guidelines (CPTGs). Based on scientific evidence, the HTA is an instrument used to assess the impacts and consequences of the use of health technologies, in the short and long term. It is a multidisciplinary process that gathers economic, ethical, clinical and organizational information, taking into account its effectiveness and efficiency.

In 2014, after an assessment by the Conitec, the Ministry of Health incorporated four clinical indications of the technique to the SUS: clinical staging of potentially resectable non-small cell lung cancer; detection of colorectal cancer metastasis, exclusively hepatic and potentially resectable; staging and assessment of treatment response for Hodgkin's Lymphoma; and Non-Hodgkin's Lymphoma [6]. Before inclusion, the right to undergo the exam for those who did not have health insurance and could not pay was through the courts [7].

According to Vidal (2018), the legal route is one of the most effective strategies to fulfill (or rectify non-compliance) the right to health; secure and guarantee access to medical procedures [8]. According to a study carried out by the Institute of Education and Research (INSPER), at the request of the National Council of Justice (NCJ), the number of annual cases related to health in the first instance, in the period from 2009 to 2017, tripled. Also, according to study data in the period between 2010 and 2016, there was a 10-fold increase in the amount spent by the SUS in lawsuits, in 2016 alone the amount surpassed the 1.3 billion reais mark. The procedures for orthotics, prostheses and auxiliary means (the category in which PET-CT is included) ranks second in terms of expenses claimed by court [9]. Therefore, this disorderly growth and the imposition of unplanned expenses, which range from the municipal to the federal level, have had a significant impact on the

management of the SUS. This fact can result in inefficiency of the services provided, since, to cover these extra demands, it is necessary to reallocate funds from other programs [9].

Since 2014, there has been no inclusion of new indications for SUS coverage. ANS increased the number of PET-CT procedures from three to nine [10]. In this scenario, considering PET-CT as a recent, complex and high-cost technology, the present study aims to raise a discussion about the diagnostic potential of the ^{18}F -PET-CT method and the need to include other clinical indications for reimbursement by SUS.

2. MATERIALS AND METHODS

In this work, to support the discussion about the potential diagnosis of ^{18}F -PET-CT and the need to expand its offer by the SUS, a database was created for these procedures performed in a private manner and with agreements at the Molecular Technology Center - Faculty of Medicine/UFMG (CTMM-FM/UFMG). The research was authorized by the Research Ethics Committee – CEP-UFMG, CAAE 3656619.7.0000.5149. Data were obtained by consulting the medical records of patients who underwent ^{18}F -PET-CT examination in the period from 2012 to 2019. The following information was collected: date of examination, date of birth, gender, age, type of cancer (in the case of cancer patients) and clinical indication. Data were stored in tables and later worked in the Infogram® program, where graphs were generated to facilitate the interpretation of the collected information.

3. RESULTS AND DISCUSSION

We were observed that of the total number of exams performed, 94.14% were exams aimed at oncological cases and only 4.86% corresponded to non-oncological clinical indications. Analyzing the profile of cancer exams performed at the CTMM (Figure 1), it is observed that Non-Hodgkin's Lymphoma (NHL) has the greatest demand for exams, followed by colon cancer; Hodgkin's Lymphoma (HL); breast cancer; lung cancer; ovarian cancer; and diffuse lymphoma (DL), respectively. Regarding the clinical indication, we observed that staging was present in most of the

requests, followed by the assessment of therapeutic response; diagnosis; recurrence evaluation; evaluation of disease activity; and research of metastasis, respectively.

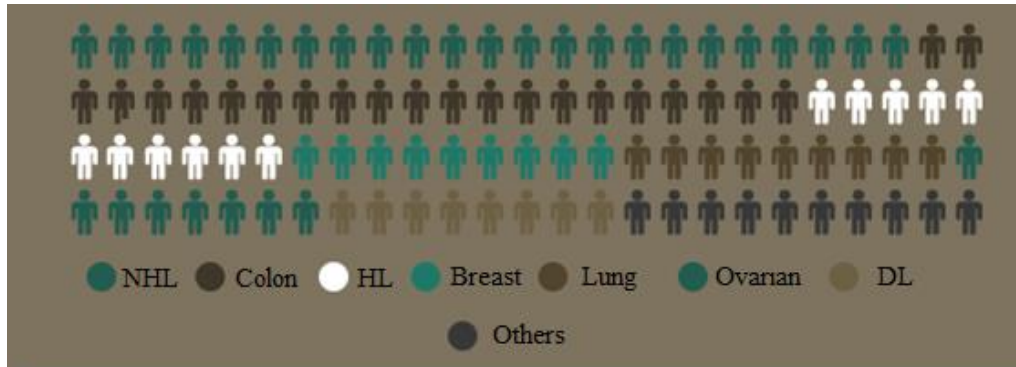


Figure 1: Clinical indications of ¹⁸F-PET-CT exams performed by type of cancer. Source: Produced by the authors with the data collected.

By analyzing the information, we observed that the age group that most demanded exams was the adult (aged between 31 and 71), followed by the children-young people (aged between 7 and 31 years old) and age group between 72 and 88 years, respectively. The mean age of patients was 55 years, with a very similar distribution per year; only in 2018 there was a greater discrepancy, the average age was 70 years. It was also found that exams with diagnostic indication of Limphoma prevailed, both in younger and older patient’s cases. With regard to distribution by sex, we observed the prevalence of demand for exams among females.

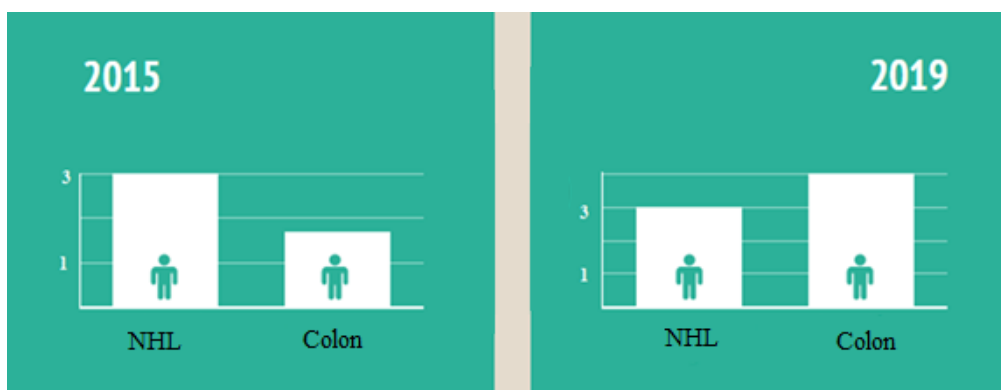


Figure 2: Comparison between the numbers of exams performed with diagnostic indication associated with NHL and colon cancer for the years 2015 and 2019. Source: Produced by the authors with the data collected.

We performed a comparison between the years 2015-2019 of tests performed for diagnostic investigation of NHL and colon cancer cases. This is because in 2014 there was the inclusion in the SUS reimbursement list for tests related to NHL, but not colon cancer. The intention is to verify a change in the number of exams performed and paid in a particular way for these diagnostic indications, demonstrating the impact for those assisted by the SUS.

Analyzing the Infographic in Figure 2 we can be seen that even with its inclusion in the SUS reimbursement table in 2014, both Non-Hodgkin Lymphoma and colon cancer continue to be the main exams performed in a particular way in the CTMM-FM/UFMG. The explanation for this increase may lie in the relevance of the method for investigating these pathologies, which results in greater prescriptions made by physicians. However, due to the delay in the authorization of the procedure by the SUS, some patients choose to undergo the exam on a private basis. The growth of private payments for diagnostic investigations related to colon cancer suggests that there is a diagnostic value in the technique, although not foreseen as strategic for health, in the context of public health, since it is not reimbursed by the SUS.

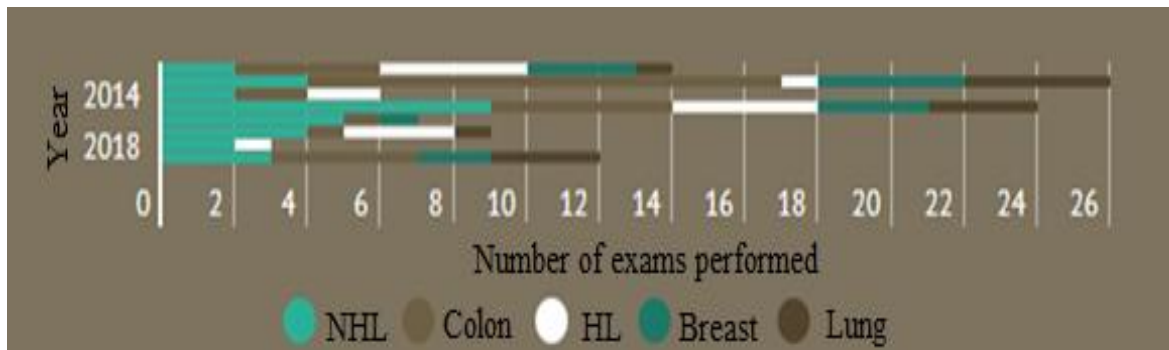


Figure 3: Evolution of the distribution of the number of exams by diagnostic indication in the studied period.

Source: Produced by the authors with the data collected.

The graph represented in Figure 3 shows the variation of exams per year between 2012 and 2019 for the most incident types of cancer in patients treated at the CTMM –FM/UFMG in a private form. Analyzing the graph, we notice that in 2013 there is a prevalence of colon cancer assessment, in 2014 there is a balanced distribution. In the following years, even with the increase in SUS coverage, Non-Hodgkin's Lymphoma was the one that had the greatest demand.

In a recent study, Hyland et al. (2020) pointed out that the value of PET/CT for staging non-small cell lung cancer is well established and considered cost-effective. On the other hand, they explored the study practices for staging at four cancer centers in the United States of geographically different patients with high molecular risk stage II-III breast cancer. They sought to determine the clinical value and cost-effectiveness of PET/CT as an initial staging procedure compared to standard imaging. They concluded the need for greater awareness of the impact of staging on patients, cost variation, and the ability to set prices at the institutional level to keep PET/CT competitive with other diagnostic techniques [11]. As an example of this study, we observe the need for in-depth study of the potential of the technique, since the results obtained point to an important diversity of applications.

4. CONCLUSION

After analyzing the results, it is concluded that, in general, the non-oncological applications of ^{18}F -PET-CT are still low, even with studies that prove the method's effectiveness. With regard to oncological applications, ^{18}F -PET-CT has established itself as an effective method for diagnosing functional imaging, especially in staging, in evaluating therapeutic response and evaluating relapse. Even with the list of clinical recommendations drawn up by competent entities, the coverage of the procedure by the SUS is deficient. Studies aimed at incorporating new clinical indications into the SUS are needed, in order to allow a better use of the diagnostic potential of the PET-CT modality. In addition to guaranteeing greater access for the population to this diagnostic modality, providing a more accurate diagnosis and thus avoiding unnecessary burdens on the SUS with legal proceedings.

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