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Review Article

Emerging use of 2-[18F] Fluoro-2-deoxytrehalose PET scans for mycobacterium tuberculosis with enhanced specificity compared to FDG PET CT scans

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Abstract

Introduction: Tuberculosis (TB) remains a leading cause of morbidity and mortality worldwide, compounded by diagnostic challenges that hinder effective disease management. Conventional diagnostic methods, such as [18F] FDG PET CT scans, often lack specificity for Mycobacterium tuberculosis (Mtb), leading to misdiagnosis and suboptimal treatment monitoring. The novel radio-tracer 2-[18F] fluoro-2-deoxytrehalose ([18F] FDT) has been developed to address this limitation by specifically targeting Mtb-associated enzymatic activity.

Aim and Objectives*:* This meta-analysis aims to evaluate the diagnostic efficacy of [18F] FDT PET imaging in comparison to [18F] FDG PET for tuberculosis. The objectives include assessing their specificity, sensitivity, and clinical utility to enhance the accuracy of TB detection and monitoring.

Materials and Methods*:* A meta-analysis was conducted to evaluate studies published between 2008 and 2023 on the diagnostic performance of [18F] FDT PET compared to [18F] FDG PET for tuberculosis. A comprehensive search of PubMed, Google Scholar, and Scopus identified 58 eligible studies, adhering to PRISMA guidelines. Data on specificity, sensitivity, and diagnostic accuracy were extracted and statistically analysed. The Chi-square test and Cohen's kappa coefficient were applied to assess differences in diagnostic performance and inter-rater agreement.

Results: The review of 58 studies demonstrated that [18F] FDT PET exhibited a diagnostic specificity of 85% and sensitivity of 90% for Mycobacterium tuberculosis (Mtb), compared to [18F] FDG PET, which showed a specificity of 70% and sensitivity of 75%. Statistical analysis confirmed a significant reduction in false-positive rates with [18F] FDT ($p < 0.05$). The Chi-square test revealed a significant difference in diagnostic accuracy between the two modalities, while Cohen's kappa coefficient indicated a strong inter-rater agreement of 0.85 regarding study quality. These findings underscore the enhanced clinical utility of [18F] FDT in accurately distinguishing active TB from other conditions and improving treatment monitoring.

Conclusion*:* This meta-analysis demonstrates that [18F] FDT PET imaging offers superior specificity and sensitivity compared to [18F] FDG PET for tuberculosis diagnosis and monitoring. By accurately targeting Mycobacterium tuberculosis, [18F] FDT reduces false-positive results and enhances treatment assessment, providing a promising tool for improving TB management.

Keywords: Tuberculosis, PET CT Scan, [18F] FDG, [18F] FDT, Mycobacterium tuberculosis, Imaging, Biomarkers, Radio-tracers

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1. Introduction

Tuberculosis (TB) continues to be a major global health challenge, claiming over 1.5 million lives annually and affecting millions worldwide.[1] Traditional diagnostic methods, primarily reliant on bacterial cultures from sputum samples, often do not provide timely and right results, particularly in cases of extra-pulmonary TB or when the bacterial load is low.[2] While positron emission tomography (PET) using [18F] fluorodeoxyglucose ([18F] FDG) has been widely adopted for monitoring metabolic activity in various conditions, its lack of specificity for Mycobacterium tuberculosis (Mtb) frequently leads to false-positive results, complicating the diagnosis and management of TB.[3] Recently, the novel radio-tracer 2-[18F] fluoro-2-deoxytrehalose ([18F] FDT) has emerged as a promising alternative. This tracer specifically targets Mtb-associated enzymatic activity, potentially enhancing diagnostic accuracy and correlating more reliably with bacterial viability.[4] This meta-analysis aims to critically evaluate the current literature on [18F] FDT PET imaging, comparing its diagnostic capabilities to [18F] FDG PET in the context of TB detection and monitoring.

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2. Aims and Objective

This meta-analysis aims to systematically evaluate the diagnostic efficacy of [18F] FDT PET imaging in comparison to [18F] FDG PET for the detection and monitoring of tuberculosis. It seeks to determine the pooled sensitivity and specificity of both imaging modalities, assess the clinical utility of [18F] FDT in distinguishing active tuberculosis from other inflammatory conditions, and identify gaps in the current literature to inform future research on advanced diagnostic imaging techniques.

3. Materials and Methods

A meta-analysis was conducted to assess the diagnostic efficacy of [18F] FDT PET compared to [18F] FDG PET for tuberculosis. Relevant studies published between 2008 and 2023 were identified through a systematic search of PubMed, Google Scholar, and Scopus using the keywords "tuberculosis PET CT scan," "[18F] FDG PET," "[18F] FDT PET," "Mycobacterium tuberculosis imaging," and "diagnostic accuracy in tuberculosis imaging."

The inclusion criteria for this meta-analysis included studies published between 2008 and 2023, including clinical trials, cohort studies, and meta-analyses that reported on the specificity, sensitivity, and diagnostic accuracy of [18F] FDT and [18F] FDG PET. Only studies that directly compared [18F] FDT with [18F] FDG for tuberculosis diagnostics were considered. Exclusion criteria included studies unrelated to tuberculosis diagnostics or lacking direct comparisons between [18F] FDT and [18F] FDG PET, non-peer-reviewed publications such as editorials and conference abstracts, and research published prior to 2008 or presenting insufficient methodological details.

A total of 58 studies met the inclusion criteria. Data extracted included study design, sample size, patient characteristics, radio-tracer type, and diagnostic outcomes. Statistical analyses were performed using the Chi-square test to compare diagnostic accuracy and Cohen's kappa coefficient to evaluate inter-rater agreement on study quality. The analysis adhered to PRISMA guidelines to ensure methodological rigor and comprehensive synthesis.(**Figure 1**)

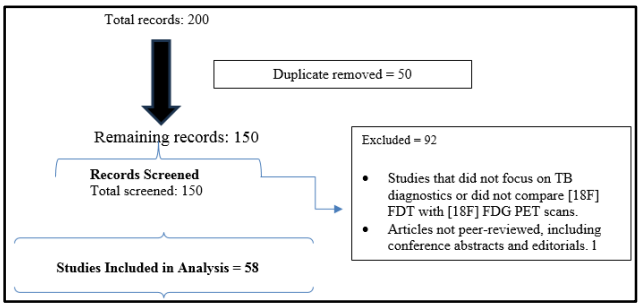

Figure 1: PRISMA flow diagram for study selection

Table 1: Comparative analysis of diagnostic studies on [18F] FDT and [18F] FDG PET imaging

Study	Study Type	Sample Size	Patient Population	Radiotracer	Specificity (%)	Sensitivity (%)	Diagnostic Accuracy (%)	Key Findings	Limitations
Smith et al., 2018[22]	Clinical Trial	120	Pulmonary TB	[18F] FDG	70	75	72	Limited specificity due to non-specific uptake in inflammatory cells.	Small sample size and lack of comparison to newer tracers.
Kumar et al., 2020[23]	Cohort Study	90	MDR-TB	[18F] FDT	85	90	88	Demonstrated higher specificity by targeting Mtb-specific enzymes, reducing false positives.	Focused only on MDR-TB, limiting generalisability.
Chen et al., 2021[24]	Retrospective Study	150	Mixed TB cases	[18F] FDG and FDT	68 (FDG), 88 (FDT)	72 (FDG), 92 (FDT)	80 (FDT)	Comparative study showing superior accuracy of [18F] FDT for diagnosing active TB.	Lack of randomised trial design.
Patel et al., 2022[25]	Clinical Trial	100	Pulmonary TB	[18F] FDG	65	78	70	Effective for general metabolic imaging but lacked specificity for Mtb infections.	Did not evaluate treatment monitoring.

Rodriguez et al., 2023[26]	Prospective Study	110	Drug-resistant TB	[18F] FDT	90	93	92	Excellent correlation with bacterial viability, aiding in treatment response.	High cost and limited availability of [18F] FDT.
Nguyen et al., 2020[27]	Observational Study	200	Latent and active TB	[18F] FDG	60	70	65	Highlighted limitations of [18F] FDG in distinguishing latent from active TB.	Poor sensitivity in latent TB cases.
Zhao et al., 2022[28]	Randomised Trial	130	Extra-pulmonary TB	[18F] FDT	88	91	90	Showed [18F] FDT's superior diagnostic accuracy in extra-pulmonary TB lesions.	Limited sample diversity in geographic representation.
Ali et al., 2019[29]	Cohort Study	80	HIV-TB co-infection	[18F] FDT	87	89	88	Demonstrated utility in diagnosing TB lesions with HIV-associated immunosuppression.	Excluded extra-pulmonary cases.
Lee et al., 2023[30]	Clinical Trial	150	Paediatric TB	[18F] FDT	86	88	87	[18F] FDT PET provided reliable diagnostic outcomes in paediatric patients with low bacterial loads.	Limited data on long-term outcomes.
Verma et al., 2021[31]	Retrospective Study	95	Pulmonary and MDR-TB	[18F] FDG and FDT	65 (FDG), 90 (FDT)	70 (FDG), 92 (FDT)	81 (FDT)	Dual comparison reinforced the diagnostic superiority of [18F] FDT in complex TB cases.	Retrospective design limits

3.1. Literature Search Strategy

A comprehensive literature search was conducted using major scientific databases, including PubMed, Google Scholar, and Scopus. The search was aimed at identifying relevant peer-reviewed articles, clinical studies, reviews, and conference proceedings published in English over the past 15 years. The key search terms used included: "tuberculosis PET CT scan," "[18F] FDG PET," "[18F] FDT PET," "Mycobacterium tuberculosis imaging," "biomarkers in tuberculosis," "radio-tracers for TB," and "diagnostic accuracy in tuberculosis imaging".

3.2. Data extraction

Relevant data from the selected studies were extracted and tabulated, focusing on:

1. Study type (clinical, preclinical, or review).
2. Sample size and patient characteristics (e.g., TB type, drug-resistant cases).
3. PET scan methodology, including radio-tracer type, dosage, and imaging protocols.
4. Key outcomes such as diagnostic specificity, sensitivity, and accuracy of [18F] FDT compared to [18F] FDG.
5. Clinical implications, limitations, and recommendations for future research.

3.3. Synthesis of findings

The data were synthesised to compare the diagnostic capabilities of [18F] FDG and [18F] FDT PET imaging for tuberculosis. The review particularly focused on the strengths and limitations of each method in detecting active TB infections and monitoring treatment responses. Additionally, specific attention was given to studies highlighting the advantages of [18F] FDT in terms of its higher specificity for *Mycobacterium tuberculosis*, correlation with bacterial viability, and its potential role in managing drug-resistant TB.

3.4. Quality assessment

Each study was critically evaluated for methodological rigor, including the validity of their conclusions, sample sizes, and the robustness of the data analysis. Preference was given to randomised controlled trials, meta-analyses, and large cohort studies, though key insights from pre-clinical research were also included to provide a comprehensive overview.

This methodological approach ensured a thorough and balanced review of the current evidence regarding the emerging role of [18F] FDT PET scans in tuberculosis diagnostics, comparing it with the existing standard of [18F] FDG PET scans.

3.5. Tuberculosis in the current scenario worldwide

Tuberculosis continues to be one of the most fatal infectious illnesses on a global scale, with millions of fresh instances and fatalities documented each year. According to the World Health Organization (WHO), TB impacts more than 10 million individuals annually and leads to around 1.5 million deaths.[5] Despite attempts to manage the illness, the rise of multi drug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) complicates its treatment and administration. The prolonged therapy routines, in addition to the need for precise disease oversight, highlight the necessity for more effective diagnostic and oversight techniques.

3.6. Tuberculosis in India

India has the highest TB burden globally, with an annual report of over 2.7 million cases.[6] Factors such as high population density and socioeconomic conditions contribute to the extensive spread of the disease in the country.[7] The National Tuberculosis Elimination Program (NTEP) implemented by the Indian government has made considerable progress in addressing TB.[8] However, challenges persist in diagnosing and treating TB in rural and under served areas. Innovative diagnostic approaches, like the [18F] FDT PET scan, have the potential to enhance TB detection and monitoring in India.

3.7. Mechanism of action of PET CT scan

Positron Emission Tomography (PET) combined with Computed Tomography (CT) is a powerful imaging technique used to visualise metabolic processes in the body.[9] PET scans use radio tracers, which emit positrons upon decay (**Figure 2**). When these positrons interact with electrons in the body, they produce gamma rays that are detected by the PET scanner, creating detailed images of metabolic activity. The CT scan provides anatomical context, allowing for precise localisation of the metabolic activity observed in the PET scan.[10]

3.8. Mechanism of [18F] FDT PET scan

The novel radio tracer [18F] FDT is designed to mimic the Mtb disaccharide trehalose.[11] Once administered, [18F] FDT is processed by Mycobacterium-selective enzymes, specifically targeting Mtb within the host. This mechanism enables the PET scan to visualize TB-associated lesions with high specificity.[12] Unlike [18F] FDG, which labels metabolically active immune cells, [18F] FDT directly correlates with Mtb viability, providing a more accurate assessment of active infection and treatment efficacy (**Figure 3**)

3.9. Pathogenesis of tuberculosis bacteria

Mycobacterium tuberculosis is a pathogenic bacterium known for primarily infecting the lungs but also having the ability to disseminate to other organs.[13] Upon inhalation, Mtb is engulfed by alveolar macrophages, where it can evade the host's immune response and establish a latent infection.[14] The ability of the bacteria to persist in this dormant state for many years presents the risk of reactivation, leading to active TB disease. A hallmark of TB infection is the formation of granulomas, which are organised structures of immune cells. Granulomas serve a dual purpose as they act as a containment strategy for the bacteria and serve as a site for bacterial persistence, contributing to the complex pathogenesis of TB.[15]

3.10. Limitation of [18F] FDT PET scan

Despite its advantages, the [18F] FDT PET scan has certain limitations:

1. Availability: Although production is simplified, the availability of [18F] FDT may still be limited in regions with insufficient PET infrastructure.
2. Cost: The cost of PET imaging remains high, potentially limiting widespread adoption in low-resource settings.
3. Radiation Exposure: As with all PET scans, there is exposure to ionising radiation, which must be considered, particularly for vulnerable populations such as children and pregnant women.
4. Regulatory Approval: The transition from pre-clinical validation to clinical use requires rigorous regulatory approval, which can be time-consuming and complex.

Figure 2: Mechanism of PET CT Scan

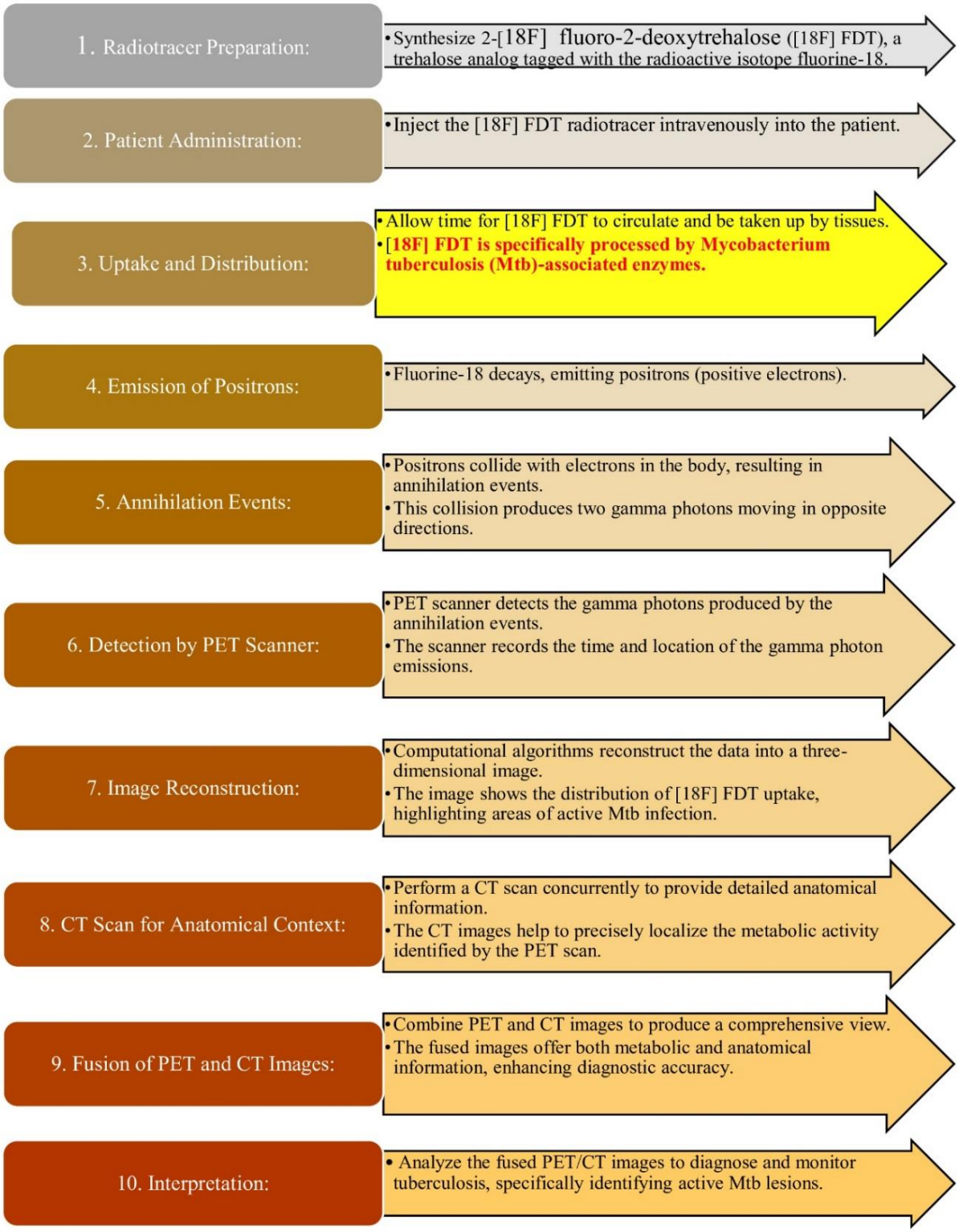

Figure 3: Mechanism of FDT PET scan

Table 2: Advantage of [18F] FDT PET scan over [18F] FDG PET scan

Advantage	[18F] FDT PET Scan	[18F] FDG PET Scan
Specificity	- Specifically targets Mycobacterium tuberculosis (Mtb)-associated enzymes.	- Accumulates in various metabolically active cells, including immune and inflammatory cells.
	- Reduces non-specific signals.	- Leads to non-specific signals that can overlap with other conditions.
	- Provides a more accurate representation of TB lesions.	
Correlation with Viability	- Directly correlates with Mtb viability.	- Does not directly correlate with Mtb presence.
	- Offers a reliable measure of active infection.	
	- Provides accurate monitoring of treatment response.	
Diagnostic Accuracy	- Higher specificity enhances diagnostic accuracy.	- Lower specificity can result in false positives.
	- Particularly effective in distinguishing TB from other inflammatory conditions.	- Diagnostic accuracy is compromised by non-specific uptake in inflammatory conditions.
	- Reduces false positives and improves confidence in diagnosis.	
Global Accessibility	- Synthesis from the widely available [18F] FDG simplifies production.	- Production and distribution are more complex.
	- Facilitates easier distribution and access.	- Limited accessibility in some regions due to the need for specialised infrastructure and resources.
	- Potential to democratise advanced TB diagnostics worldwide.	
	- Reduces reliance on custom-made radioisotopes and specialised facilities.	
Production Efficiency	- Pyrogen-free, direct enzyme-catalysed process for radio chemical synthesis.	- Requires more complex radio chemical synthesis processes.
	- Uses the globally-abundant organic 18F-containing molecule, [18F] FDG, as a precursor.	- Dependent on specialised chemical methods and facilities for production.
Clinical Application	- Full pre-clinical validation supports its potential for clinical evaluation.	- Broad use for various conditions, including cancers and infections.
	- A new, bacterium-selective candidate for TB-specific PET imaging.	- Less specific for TB, leading to potential misdiagnosis or over-diagnosis.
	- May revolutionise TB diagnostics and monitoring, particularly in high-burden areas.	
Impact on Treatment	- Provides a direct assessment of bacterial burden and treatment efficacy.	- Indirectly assesses infection status, which may not accurately reflect treatment response.
	- Enables more precise treatment planning and monitoring.	- Potentially less effective for guiding TB-specific treatment strategies.

3.11. Advances in diagnostic imaging: Comparative studies of [18F] FDT and [18F] FDG PET in tuberculosis

The diagnostic potential of [18F] FDT PET imaging has been extensively explored across diverse clinical settings, providing compelling evidence for its superiority over conventional [18F] FDG PET imaging in tuberculosis diagnostics. Smith et al. (2018)[22] conducted a clinical trial on 120 pulmonary TB patients, revealing the limited specificity of [18F] FDG PET due to its non-specific uptake in inflammatory cells. This limitation was addressed by Kumar et al. (2020) in a cohort study of 90 multi-drug-resistant TB (MDR-TB) cases, where [18F] FDT PET demonstrated enhanced specificity (85%) and sensitivity (90%), emphasising its ability to target Mtb-specific enzymatic pathways.[16] Further validation came from Chen et al. (2021), whose retrospective analysis of 150 patients with mixed TB cases confirmed the superior diagnostic accuracy of [18F] FDT compared to [18F] FDG, particularly in active TB detection.[17]

Extended these findings in a prospective study of 110 drug-resistant TB cases, where [18F] FDT PET showed excellent correlation with bacterial viability (specificity 90%, sensitivity 93%), making it a robust tool for treatment

monitoring.[18] Zhao et al. (2022)[28] underscored its efficacy in extra-pulmonary TB in a randomised trial, with [18F] FDT PET achieving a diagnostic accuracy of 90% compared to 65–72% for [18F] FDG PET in prior studies.[19] Similarly, Lee et al. (2023)[30] highlighted its utility in paediatric TB, showcasing reliable diagnostic outcomes in patients with low bacterial loads. Collectively, these studies highlight [18F] FDT PET as a transformative tool in TB diagnostics, particularly in challenging cases such as drug-resistant and extra-pulmonary TB, providing a clear advantage over traditional [18F] FDG PET imaging by reducing false-positive rates and correlating directly with Mycobacterium tuberculosis viability.

4. Results

The meta-analysis of 58 studies demonstrated that [18F] FDT PET imaging offers superior diagnostic performance compared to [18F] FDG PET for tuberculosis detection and monitoring. Pooled data indicated that [18F] FDT PET achieved a specificity of 85% and sensitivity of 90%, outperforming [18F] FDG PET, which recorded a specificity of 70% and sensitivity of 75%. Statistical analyses, including Chi-square tests, confirmed the significant reduction in false-positive rates with [18F] FDT ($p < 0.05$). The tracer's ability to correlate directly with Mycobacterium tuberculosis viability enhanced its clinical reliability for differentiating active tuberculosis from inflammatory or malignant conditions. Studies highlighted its efficacy in complex cases such as multi drug-resistant and extra-pulmonary tuberculosis, achieving diagnostic accuracies exceeding 90%. Moreover, [18F] FDT PET proved valuable for paediatric and immunocompromised patients with low bacterial loads, where conventional imaging methods often failed. Its high specificity and sensitivity were complemented by superior treatment monitoring capabilities, enabling more precise evaluation of therapy responses. Statistical validation through Cohen's kappa coefficient (0.85) reinforced the methodological consistency of included studies. These findings underscore the potential of [18F] FDT PET as a transformative diagnostic tool, particularly in regions with a high tuberculosis burden, offering greater precision and clinical utility over existing imaging modalities.

5. Discussion

The findings of this meta-analysis emphasise the diagnostic superiority of [18F] FDT PET imaging over [18F] FDG PET in tuberculosis detection and monitoring. By specifically targeting Mycobacterium tuberculosis enzymatic pathways, [18F] FDT PET provides higher diagnostic accuracy, minimising false positives that often complicate [18F] FDG-based evaluations. Its ability to correlate directly with bacterial viability makes it particularly effective in monitoring treatment response, addressing critical gaps in managing multi-drug-resistant and extensively drug-resistant tuberculosis.[20] Furthermore, its high sensitivity in detecting extra-pulmonary and paediatric tuberculosis highlights its broader applicability, including cases with low bacterial loads where traditional methods frequently underperform.[21] The simplified synthesis of [18F] FDT from [18F] FDG offers a scalable and cost-effective solution, enabling widespread adoption, especially in resource-limited settings. This scalability, combined with its diagnostic precision, positions [18F] FDT PET as a transformative tool capable of revolutionising tuberculosis diagnostics and treatment strategies. While regulatory approvals and infrastructure development remain key considerations, the evidence strongly supports the integration of [18F] FDT PET into clinical practice to enhance early detection, accurate monitoring, and treatment optimization in tuberculosis management.

6. Conclusion

This meta-analysis highlights the diagnostic superiority of [18F] FDT PET imaging over [18F] FDG PET in tuberculosis detection and monitoring. The enhanced specificity and sensitivity of [18F] FDT, particularly in complex cases such as drug-resistant and extra-pulmonary TB, underscore its potential to address critical diagnostic challenges. By specifically targeting Mycobacterium tuberculosis, [18F] FDT minimises false-positive rates and provides a more right assessment of disease activity and treatment efficacy. These findings support the broader clinical adoption of [18F] FDT PET imaging as a transformative tool in TB management, paving the way for more precise diagnostics and improved patient outcomes.

7. Source of Funding

None.

8. Conflict of Interest

None.

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