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Head-to-head comparison of [^{68}Ga]Ga-FAP-2286 and [^{18}F]FDG PET/CT in inoperable lung cancer: A prospective pilot study

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ABSTRACT

Introduction: Fibroblast activation protein inhibitor (FAPI) radiotracers have demonstrated high tumor uptake across various malignancies. Comparative data with [^{18}F]FDG in lung cancer are limited. This study evaluates uptake characteristics of [^{68}Ga]Ga-FAP-2286versus [^{18}F]FDG in inoperable lung cancer and explores implications for future FAP-targeted radioligand therapy.

Methods: This prospective pilot study included seven patients with histologically confirmed inoperable lung cancer who underwent standard [^{18}F]FDG PET/CT followed by [^{68}Ga]Ga-FAP-2286 PET/CT within one month. SUVmax and standardized uptake (lesion-to-blood-pool ratio) were measured for primary tumors, lymph nodes, liver, bone, and adrenal metastases. Physiologic biodistribution was also assessed.

Results: Six patients had measurable residual primary tumors. [^{68}Ga]Ga-FAP-2286 showed numerically higher uptake in primary tumors compared with [^{18}F]FDG (SUVmax 5.7±2.2 vs. 5.2±0.9; standardized uptake 4.3±2.3 vs. 2.5±0.9). Mediastinal nodal uptake differences were not statistically significant. All metastatic lesions exhibited uptake above background, indicating robust targeting. [^{68}Ga]Ga-FAP-2286 biodistribution revealed high renal uptake, mild hepatic

uptake, and minimal bone-marrow activity, supporting the feasibility of future therapeutic labeling.

Conclusion: In this small prospective pilot study, [^{68}Ga]Ga-FAP-2286 demonstrated favorable uptake in primary and metastatic lung-cancer lesions with low background activity in several normal tissues. These findings are preliminary and hypothesis-generating. Larger prospective studies incorporating lesion-level analysis, standardized imaging methodology, and formal dosimetry are required before definitive conclusions can be drawn regarding diagnostic superiority or therapeutic applicability.

Keywords: Lung noplasms; Positron emission tomography computed tomography; Fibroblast activation protein; Standardized uptake value

INTRODUCTION

Lung cancer remains a leading cause of cancer-related mortality worldwide, with a substantial proportion of patients presenting with inoperable disease requiring systemic therapy [1]. The standard imaging modality for staging, restaging, and treatment response assessment in lung cancer is [^{18}F]FDG PET/CT, which exploits the increased glucose metabolism of malignant cells [2]. However, while [^{18}F]FDG PET/CT has become the standard of care in nuclear medicine for lung cancer imaging, a major gap remains. Unlike certain other tumor types—such as neuroendocrine tumors and prostate carcinoma—there is currently no approved nuclear medicine therapeutic radioligand in lung cancer that builds on [^{18}F]FDG imaging [3].

In recent years, radiopharmaceuticals targeting the fibroblast activation protein (FAP) have shown promising imaging performance across a variety of malignancies, often outperforming [^{18}F]FDG in lesion detection, tumor-to-background contrast, and sensitivity for nodal or metastatic disease. Meta-analyses and multicenter experiences suggest that FAPI tracers provide superior detection in cancers with desmoplastic stroma [3, 4]. Moreover, early clinical reports in lung cancer indicate that FAPI PET/CT can detect more lymph node and bone metastases than [^{18}F]FDG [3-5].

Our previous experience with FAPI in papillary thyroid carcinoma demonstrated its high tumor-to-background ratio and potential utility in poorly FDG-avid or dedifferentiated lesions [6]. These findings support broader oncologic applications of FAPI imaging beyond the classical FDG-avid tumors.

The cyclic peptide tracer [^{68}Ga]Ga-FAP-2286 has been evaluated in direct head-to-head comparisons with [^{18}F]FDG. In one prospective study, [^{68}Ga]Ga-FAP-2286 yielded higher SUVmax values and improved nodal and metastatic lesion detection compared with [^{18}F]FDG [5]. The longer tumor retention time of the FAP-2286 peptide scaffold also makes it suitable for radiolabeling with therapeutic isotopes such as lutetium-177, raising the possibility that the same ligand used for imaging could also be used for therapy (theranostics) in lung cancer [7].

Another key rationale for exploring new therapeutic nuclear medicine options in lung cancer lies in the high prevalence of chemoresistance and treatment failure in advanced disease. Resistance to systemic therapies-including chemotherapy, targeted therapy, and immunotherapy-is highly common, with in-vitro studies reporting extreme chemotherapy resistance in up to 31–75% of NSCLC samples [8, 9]. Such rates imply a substantial unmet need for alternative therapeutic strategies, similar to the established role of radionuclide therapy in neuroendocrine tumors ([^{177}Lu]Lu-DOTATATE) and prostate cancer ([^{177}Lu]Lu-PSMA) [10].

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Therefore, the present study aims to compare the uptake characteristics of [^{68}Ga]Ga-FAP-2286 versus [^{18}F]FDG in lung cancer, encompassing both primary tumors and metastatic sites. By quantifying differences in uptake, lesion detection, and tumor-to-background ratios, we seek to evaluate whether [^{68}Ga]Ga-FAP-2286 offers a favorable imaging profile that could justify future therapeutic trials of [^{177}Lu]Lu-FAP-2286 in lung cancer.

METHODS

This prospective exploratory pilot study included seven patients (six males and one female) with pathologically confirmed lung cancer who were referred for routine [^{18}F]FDG PET/CT imaging between November 2024 and March 2025. Histopathological subtypes consisted of five adenocarcinomas and two squamous cell carcinomas. The patients were diagnosed to have inoperable disease and none had previously undergone surgical tumor resection. Two patients were examined for initial staging, while five were evaluated after completion of chemotherapy for assessment of treatment response. Four patients had also received external-beam radiotherapy before study inclusion.

Eligible participants were required to have a histologically verified diagnosis of primary lung cancer and an indication for standard-of-care [^{18}F]FDG PET/CT .

All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by Research Ethics Committee of Tehran University of Medical Sciences (IR.TUMS.IKHC.REC.1403.023).

All patients underwent paired [^{18}F]FDG and [^{68}Ga]Ga-FAP-2286 PET/CT examinations using the same PET/CT system (Discovery IQ, GE Healthcare, Waukesha, WI) according to routine clinical protocols. Both radiotracers were produced and quality-controlled by Pars Isotope (Karaj, Iran). No surgical intervention, biopsy, chemotherapy or radiotherapy was administered between the two PET/CT examinations. According to institutional practice, PET/CT examinations were performed at least 1 month after chemotherapy and at least 2 months after radiotherapy.

For the[^{18}F]FDG PET/CT examination patients fasted for at least six hours, and blood glucose levels were confirmed to be below 200 mg/dL at the time of tracer injection. Approximately 5–7 MBq/kg of [^{18}F]FDG was administered intravenously, and image acquisition was initiated 60 minutes after injection.

The[^{68}Ga]Ga-FAP-2286 PET/CT examination was performed within one month of the [^{18}F]FDG PET/CT, as specified in the study protocol. After intravenous injection of 5–7 mCi (185–260 MBq) of [^{68}Ga]Ga-FAP-2286 whole-body imaging from the mid-thigh to the vertex was performed 60 minutes post-injection.

All PET/CT images were reconstructed using ordered-subset expectation-maximization (OSEM) algorithms. Imaging findings were independently reviewed and interpreted by two nuclear medicine specialists using Volume Viewer software on the ADW 4.7 workstation. In cases of disagreement, a third nuclear medicine specialist reviewed the images and provided the final interpretation. Tumor dimensions were measured on the CT component of the fused PET/CT images in three orthogonal planes: transaxial, anteroposterior, and craniocaudal. For each patient, the maximum standardized uptake value (SUVmax) was calculated for the primary lung tumor, mediastinal lymph nodes, and, when present, bone, liver, and adrenal metastases. For quantitative analysis, when multiple lesions were present within the same lesion category, the lesion

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demonstrating the highest uptake was selected as the representative lesion for each tracer. For osseous lesions, both the lesion with the highest uptake and the largest lesion were additionally evaluated. In addition, SUVmax was measured for the descending aorta (representing blood pool) and for the right hepatic lobe in regions free of tumor infiltration. To normalize the inter-patient variation for systemic activity, a standardized SUV ratio (hereafter referred to as "standardized SUV") was calculated as the ratio of the target lesion SUVmax to the blood-pool SUVmax.
For each lesion type, the uptake parameters derived from the [^{18}F]FDG and [^{68}Ga]Ga-FAP-2286 scans were compared pairwise to assess relative tracer performance and lesion detection rates. Quantitative analyses were performed using SPSS software (version 26, IBM Corp., Armonk, NY, USA). All results are expressed as mean ± standard deviation (SD). Given the small sample size and the limited number of observations within individual lesion categories, the analysis was primarily descriptive. Continuous variables are summarized as mean ± standard deviation, and paired tracer measurements are presented descriptively for within-patient comparison. No formal inferential conclusions were drawn from subgroup comparisons.

RESULTS

Tumor characteristics

In one patient, the primary lung tumor showed marked shrinkage following treatment, with no measurable residual tumor identified on either [^{18}F]FDG or [^{68}Ga]Ga-FAP-2286 PET/CT. Mild residual uptake was observed in the treated tumor bed on both scans, with SUVmax values of 2.7 and 7.3, respectively. This uptake was interpreted as post-radiotherapy inflammatory change rather than viable residual tumor, and the patient was therefore reported as having a complete metabolic response. In the remaining six patients, measurable residual tumors were observed. Mean tumor dimensions measured on the CT component of the images were 24.7 ± 7.3 mm in the transaxial plane, 20.7 ± 4.3 mm in the anteroposterior dimension, and 27.8 ± 12.2 mm in the craniocaudal direction, corresponding to post-therapy residual disease.

[^{68}Ga]Ga-FAP-2286 biodistribution

The kidneys demonstrated the highest physiological uptake, serving as the primary target organ (SUVmax 4.7 ± 0.9). As expected, the urinary bladder also showed pronounced activity due to renal excretion. Hepatic uptake was mild (SUVmax 2.6 ± 0.7). Overall background activity was low, enabling excellent visualization of the primary lung tumor in all six patients with residual disease. Brain background uptake was negligible in all patients. Representative patient images are shown in Figure 1.

Tracer uptake comparison

Quantitative analysis showed numerically higher [^{68}Ga]Ga-FAP-2286 uptake than [^{18}F]FDG uptake in the primary lung tumors, whereas [^{18}F]FDG uptake was numerically higher in mediastinal lesions (Table 1). [^{68}Ga]Ga-FAP-2286 demonstrated numerically higher uptake than [^{18}F]FDG in primary tumors, with mean SUVmax values of 5.7±2.2 vs. 5.2±0.9, respectively.. [^{68}Ga]Ga-FAP-2286 demonstrated lower physiologic background uptake in the liver and blood pool compared with [^{18}F]FDG, suggesting a higher tumor-to-background ratio. Uptake in the primary tumors was slightly higher with [^{68}Ga]Ga-FAP-2286 (5.73 ± 2.21) than with [^{18}F]FDG (5.15 ± 1.87). The standardized uptake ratio was numerically higher for primary tumors with

[^{68}Ga]Ga-FAP-2286 than with [^{18}F]FDG (4.3 ± 2.3 vs. 2.5 ± 0.9, respectively). For mediastinal lymph nodes, the standardized uptake ratio was numerically lower with [^{68}Ga]Ga-FAP-2286 than with [^{18}F]FDG (4.7 ± 3.4 vs. 5.7 ± 1.5, respectively). For hepatic metastasis, the SUVmax was 10.1 with [^{68}Ga]Ga-FAP-2286 and 17.8 with [^{18}F]FDG, while for osseous lesions, the SUVmax was 3.5 ± 1.3 versus 7.9 ± 0.7 for the largest lesions and 5.8 ± 3.6 versus 10.3 ± 2.1 for the hottest lesions, respectively.

DISCUSSION

In our study, the main finding was that tumor uptake in the primary lung lesions was higher for [^{68}Ga]Ga-FAP-2286 than for [^{18}F]FDG . This observation suggests that [^{68}Ga]Ga-FAP-2286 may demonstrate favorable uptake characteristics in primary lung tumors; however, the small sample size precludes any conclusion regarding diagnostic superiority. Previous studies have similarly reported higher uptake of FAPI tracers compared to [^{18}F]FDG in primary tumors across various cancers, including lung cancer [11-13]. Therefore, [^{68}Ga]Ga-FAP-2286 may provide favorable imaging characteristics compared with [^{18}F]FDG in primary lung tumors, with the potential to improve tumor delineation and lesion conspicuity in lung cancer imaging.

Another important observation was that [^{68}Ga]Ga-FAP-2286 displayed low liver uptake in our cohort. These biodistribution features may be relevant to the investigation of FAP-targeted radioligand therapy (RLT), although the present study did not include dosimetric assessment. The kidneys were identified as the predominant excretory and target organ in both the current and prior biodistribution studies [14]. Further studies incorporating quantitative dosimetry are required to determine the radiation exposure of normal organs and to assess the therapeutic implications of these biodistribution characteristics.

Furthermore, in our cohort all metastases (including lymph nodes, viscera and bone) showed tracer uptake above background levels. These findings support further investigation of [^{68}Ga]Ga-FAP-2286 as an imaging agent in metastatic lung cancer and provide a rationale for evaluating its potential theranostic applications. The literature supports FAP-targeted radioligand therapy in diverse malignancies; however, the therapeutic applicability of FAP-2286 in metastatic lung cancer requires dedicated clinical and dosimetric evaluation [15].

Visually, our observations suggest a favorable target-to-background ratio for [^{68}Ga]Ga-FAP-2286 in primary and metastatic lesions, which may be relevant to its potential theranostic applications. Nonetheless, a favorable target-to-background ratio on a single static PET/CT acquisition cannot establish tumor radiation dose, normal-tissue radiation exposure, or therapeutic feasibility. Formal multi-time-point dosimetric studies will therefore be required to estimate absorbed doses and evaluate the feasibility and safety of [^{177}Lu]Lu-FAP-2286 therapy. The small sample size of our study is another limitation, and the findings should be considered hypothesis-generating rather than definitive. Further larger prospective studies incorporating dosimetry, treatment response and outcome data are needed to validate our observations.

The principal limitation of this study is the very small and clinically heterogeneous cohort. The sample size precludes robust inferential comparisons and limits generalizability. Accordingly, the findings should be interpreted as exploratory and hypothesis-generating rather than confirmatory. Another limitation is that a systematic lesion-level analysis of concordance and tracer-exclusive lesions was not performed. In addition, selecting the lesion with the highest tracer uptake as the

representative lesion when multiple lesions were present may introduce selection bias and may not fully reflect the heterogeneity of lesion-level tracer uptake.

CONCLUSION

In this prospective pilot study, [^{68}Ga]Ga-FAP-2286 demonstrated measurable uptake in primary and metastatic lung cancer lesions and favorable lesion-to-background characteristics at several sites compared with [^{18}F]FDG. However, because of the very small and clinically heterogeneous cohort, these findings should be considered exploratory and hypothesis-generating rather than confirmatory. Larger prospective studies with lesion-level analysis, standardized imaging protocols, and formal multi-time-point dosimetry are required to clarify the diagnostic performance and potential theranostic role of FAP-2286 in lung cancer.

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Table 1. The SUVmax (uptake) and SUVmax and blood pool SUVmax ratio (standardized uptake) in primary lung tumor and metastatic lesions; comparison of the [^{18}F]FDG and [^{68}Ga]Ga-FAP-2286 uptakes

		Uptake				Standardized Uptake			
	N	FAPI		FDG		FAPI		FDG	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Liver	7	2.6	0.7	2.9	0.2	-	-	-	-
Blood pool	7	1.4	0.2	2.1	0.1	-	-	-	-
Primary	6	5.7	2.2	5.2	0.9	4.3	2.3	2.5	0.9
Mediastinal	5	7.0	3.3	9.4	1.5	4.7	3.4	5.7	1.5
Non mediastinal	3	4.4	0.9	9.9	0.5	5.1	3.0	3.6	1.7
Bone (large lesion)	3	3.5	1.3	7.9	0.7	2.8	1.2	4.1	0.7
Bone (hot lesion)	3	5.8	3.6	10.3	2.1	5.3	4.6	4.7	2.6
Adrenal	1	9.6	-	23.7	-	-	-	-	-
Pleural†	1	14.9	-	24.4	-	-	-	-	-
Liver	1	10.1	-	17.8	-	-	-	-	-

†Pleural effusion and thickening

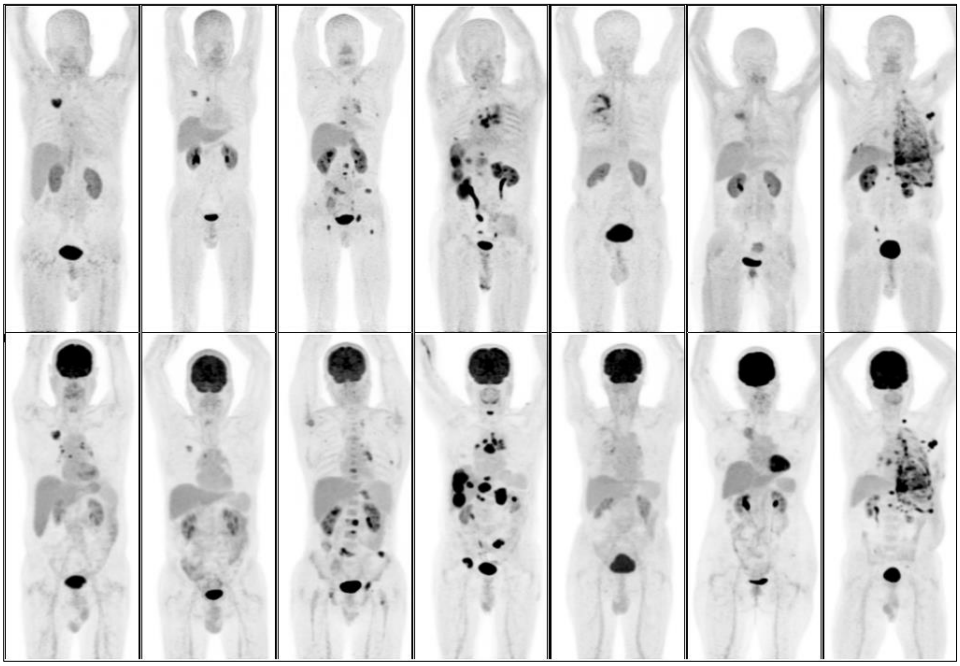


Figure 1. Comparative maximum-intensity projection (MIP) images of [^{68}Ga]Ga-FAP-2286 and [^{18}F]FDG PET/CT in all seven patients, shown as paired images for direct visual comparison. The upper row shows [^{68}Ga]Ga-FAP-2286 PET/CT images, whereas the lower row shows [^{18}F]FDG PET/CT images. The primary tumor is prominently visualized on [^{68}Ga]Ga-FAP-2286 imaging, and metastatic lesions also exhibit robust tracer accumulation. Although hepatic and blood-pool activity is comparable between the two tracers, [^{68}Ga]Ga-FAP-2286 provides superior lesion-to-background contrast. Notably, physiologic brain uptake of [^{68}Ga]Ga-FAP-2286 PET/CT is extremely low, in contrast to the high cortical uptake seen on [^{18}F]FDG PET/CT