



Functional respiratory imaging (FRI)-derived changes in pulmonary vascular morphology after a single dose of inhaled mosliciguat in a Phase 1 open-label study in healthy volunteers

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Background

- Functional respiratory imaging (FRI) is a proprietary platform used to segment the pulmonary vasculature and quantify blood vessel volumes from low-dose, thin-section chest computed tomography (CT).
- Inhaled mosliciguat is a potential first-in-class, once-daily, investigational soluble guanylate cyclase activator targeting the nitric oxide-soluble guanylate cyclase-cyclic guanosine monophosphate pathway, promoting vasodilation and potentially reducing inflammation and fibrosis and reversing vascular remodeling.
- This study aims to characterize the effect of inhaled mosliciguat on the pulmonary vasculature of healthy volunteers.

Aim

- Characterize changes to FRI-derived metrics of pulmonary vascular morphology between baseline and three hours following a single dose of inhaled mosliciguat in healthy volunteers.

Methods

- This exploratory FRI analysis was conducted during one treatment period of a Phase 1, open-label, single-center study in 8 healthy male volunteers (NCT07185321).
- Thin-section, volumetric CT was performed at maximal inspiration on a single scanner using a low-dose protocol at baseline and approximately 3 hours after a 4-mg dose of inhaled mosliciguat.
- FRI was used to produce semi-automated segmentations of the pulmonary vasculature, including separation of arteries from veins.
- Outcomes included changes from baseline in the volume of vessels <5 mm² (BV5), 5-10 mm² (BV5-10), and >10 mm² (BV10).
- Arterial, venous, and combined volumes were assessed separately.
- Change from baseline hypothesis testing was performed using Wilcoxon rank sum tests.

Results

- Eight healthy male participants were enrolled into the study; 7 participants had complete FRI data for inclusion in this analysis.
- The FRI parameters reflecting total arterial and venous blood volumes as well as in vessels with specific ranges of cross-sectional area (BV5, BV5-10, BV10) at baseline and three hours post-dose are shown in **Table 1**.
 - Three hours after a single dose of inhaled mosliciguat, participants exhibited significant increases in image-based artery volume and image-based vein volume. The magnitude of change in arterial volume was greater than that in venous volume.
- Increases in arterial and venous volumes were observed across all size ranges (BV5, BV5-10, BV10) and were greatest in small vessels (BV5), indicating a shift in distribution towards the distal pulmonary vasculature as depicted in **Figure 1**.

Figure 1. Three-dimensional vascular reconstruction illustrating changes in arterial blood volume distribution.

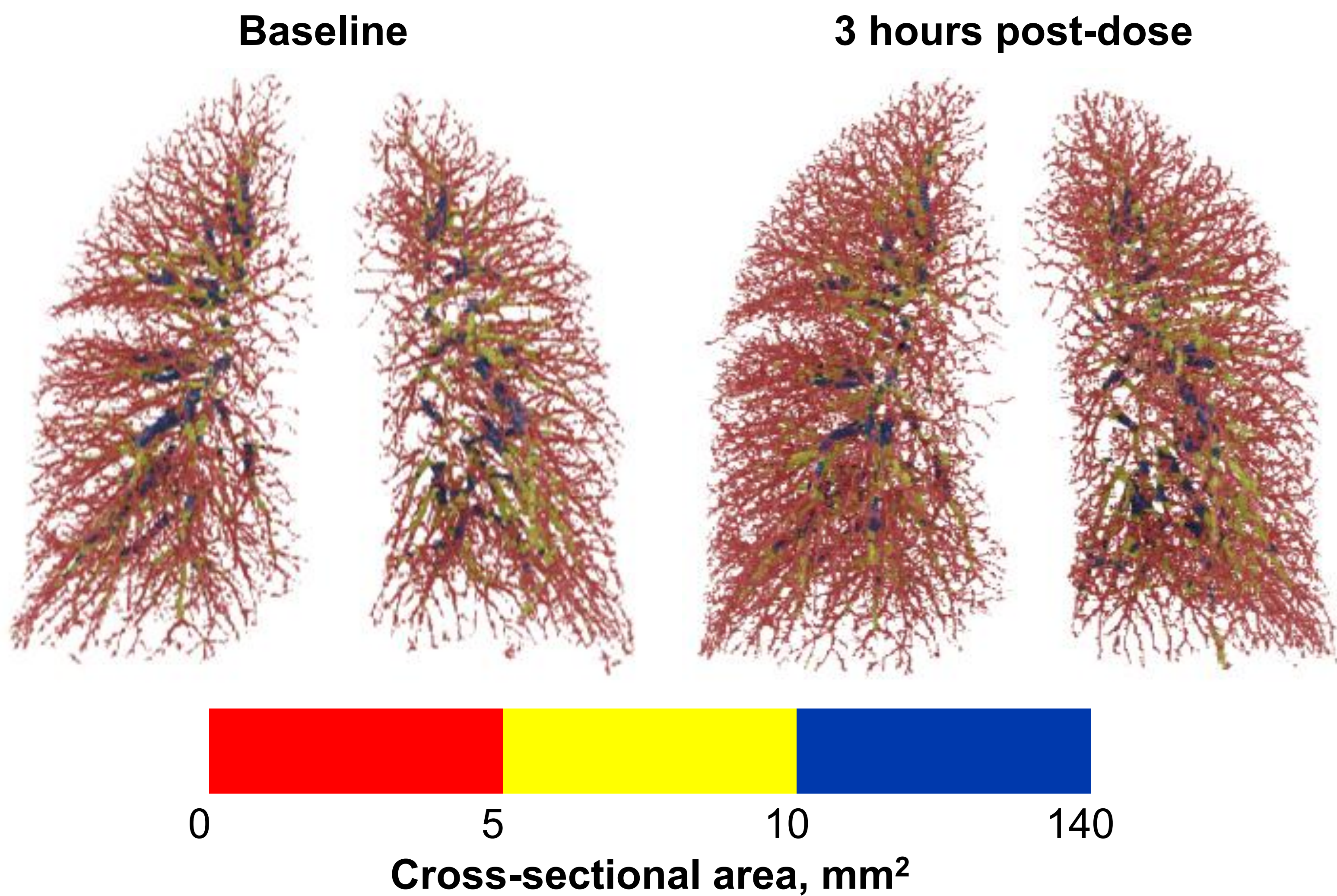


Table 1. Changes in blood vessel volume by cross-sectional area at baseline and three hours post-dose of inhaled mosliciguat.

FRI parameter	Baseline (n=8) Mean (SD)	Hour 3 (n=7) Mean (SD)	Estimated median difference	P-value
Total image-based arterial volume, mL	65.7 (15.3)	97.2 (11.3)	25.0	0.02
Total image-based venous volume, mL	64.9 (7.3)	74.2 (5.6)	7.9	0.03
BV5A, mL	43.7 (11.6)	67.7 (8.2)	18.6	0.02
BV5V, mL	38.4 (5.8)	44.4 (3.3)	3.0	0.03
BV5-10A, mL	12.6 (3.0)	17.3 (2.5)	3.6	0.02
BV5-10V, mL	13.5 (2.0)	15.8 (1.7)	1.6	0.02
BV10A, mL	9.3 (2.0)	12.0 (3.8)	2.5	0.05
BV10V, mL	12.6 (2.7)	13.7 (2.4)	1.2	0.03

Limitations

- This analysis was exploratory in nature; therefore, the small sample size, lack of a control group, and lack of correction for multiple testing indicate that further evaluation in a placebo-controlled setting is warranted to confirm the observed increase in pulmonary vascular volume after inhaled mosliciguat administration.
- Inhaled mosliciguat, administered as a single 4-mg dose, was associated with increases in image-based pulmonary arterial and venous volumes in healthy volunteers, with greater effects in arterial than in venous volumes and preferentially affecting smaller vessels.
- These findings support further evaluation of inhaled mosliciguat using FRI in participants with pulmonary hypertension associated with interstitial lung disease.

Abbreviations: BV5A, volume of pulmonary arteries <5 mm² in cross-sectional area; BV5V, volume of pulmonary veins <5 mm² in cross-sectional area; BV5-10A, volume of pulmonary arteries 5-10 mm² in cross-sectional area; BV5-10V, volume of pulmonary veins 5-10 mm² in cross-sectional area; BV10A, volume of pulmonary arteries >10 mm² in cross-sectional area; BV10V, volume of pulmonary veins >10 mm² in cross-sectional area; SD, standard deviation.

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