

A Multicenter MRI Protocol for the Evaluation and Quantification of Deep Vein Thrombosis

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Background: Compression ultrasound (CUS) is used to diagnose acute deep venous thrombosis (DVT). However, CUS cannot assess pelvic veins and cannot quantify thrombus volume. In a study of edoxaban monotherapy for acute, symptomatic DVT treatment (eTRIS), we are utilizing a novel MR venography approach using a 3D VIBE sequence with gadofosveset as a contrast agent to quantify total thrombus volume changes as an assessment of treatment efficacy.

Purpose: We utilized MRV with the long circulating contrast agent gadofosveset (Ablavar®) to establish and validate a quantitative assessment of DVT thrombus volume in a multicenter clinical trial setting. Here we demonstrate the reproducibility of the image analysis approach used for this trial.

Methods: From 10 of the 85 eTRIS subjects (evaluating the efficacy of the oral, direct factor Xa inhibitor edoxaban), total thrombus volume in the entire deep venous system was quantified (external iliac, common/superficial/deep femoral, popliteal, anterior/posterior tibial, gastrocnemius, and peroneal veins) bilaterally. Subjects were supine and imaged in three sections (pelvis/thighs/calves) using a T1W 3D gradient echo sequence before and 5 minutes after injection of 0.03mmol/kg of Ablavar®. DVT was visualized as lower signal intensity compared with surroundings on coronal post contrast images (Figure). A curved path following centerline of each vein was calculated, the vessel straightened and corresponding cross sectional images segmented by 2 observers by placing regions of interest on each reformatted imaging slice to obtain volumetric measurements of DVT. Sample images are shown in Figure 1. Intra-class correlation (ICC) and Bland Altman analysis were performed to compare the results obtained by the two readers.

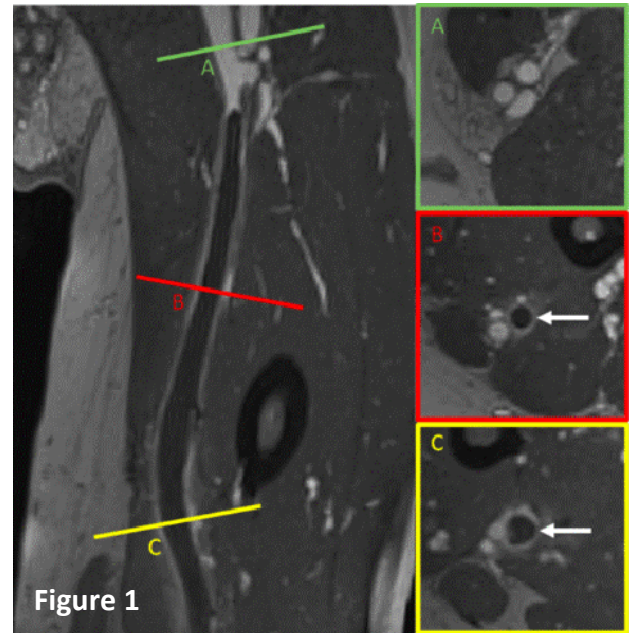


Figure 1
MRV of DVT with Ablavar. Longitudinal view (left panel) and cross-sectional views (right panels). White arrows indicate DVT.

Results: The average total thrombus volume measured by MRV with Ablavar was $3.13 \pm 6.23\text{cm}^3$. The ICC between the readers was excellent (0.98, $p < 0.001$) and Bland Altman analysis (Figure 2) revealed little bias between readers.

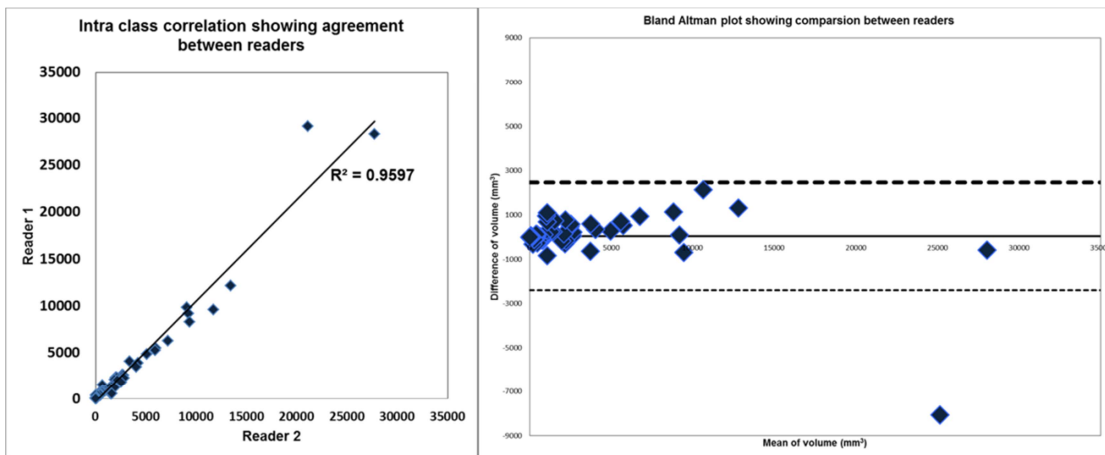


Figure 2: Intra Class Correlation and Bland-Altman Plot showing the reproducibility of the analysis for quantifying thrombus volumes of DVT in a multicenter setting.

Conclusion: MR venography with Ablavar® provides a robust and reproducible method to quantify DVT volumes in a multi-center setting and can potentially be used as a tool for quantifying DVT treatment efficacy.