The VIDIO Trial: Diagnostic and Clinical Implications on the Use of IVUS for Deep Vein Treatment

Paul J. Gagne, MD, FACS, RVT
Chief, Vascular Surgery, Norwalk Hospital
Associate Clinical Professor of Surgery, NYU
Disclosure

Consultant Philips-Volcano
Background

- 2D vein lumenography can be a source of false negatives and false positives.
- The 50% DS customary threshold of iliofemoral veins by MPV has not been validated clinically.
- Besides bringing higher diagnostic accuracy, can IVUS carry predictive value in determining clinical improvement? And under which criteria?

Venogram vs IVUS for Diagnosing Iliac vein Obstruction

• Rigorous trial assessing the role of IVUS in the diagnosis & treatment of ilio-femoral vein obstructions
  – N=100 patients
  – Prospective, single-arm
  – Multicenter (14 sites: 11 US + 3 EU)
  – Independent Core-lab* adjudication (IVUS and MPV)
  – ClinicalTrials.gov Identifier: NCT02142062

* Syntactx, NY, US

VIDIO Trial - Objectives

1. Compare the diagnostic accuracy of IVUS vs. MPV for identifying iliofemoral vein obstruction [1]
2. Assess (post-hoc) clinical predictive value of IVUS; define a baseline and procedural % Stenosis thresholds where interventional treatment is more likely to result in clinical improvement [2]

VIDIO Trial - Design

- Differences in intention to treat on the basis of the 2 imaging methods documented and concordance of measurements assessed
- MPV standardized (3 views: AP, 30° RAO and 30° LAO)
- 50% considered as “significant” stenosis threshold for DS (MPV) and CSA (IVUS)
- Stenting performed at the discretion of investigators
- Core laboratory assessments of de-identified images (MPV and IVUS) independent and blinded “read” and comparison of image results
VIDIO Trial - Methodology

• Diagnostic and predictive accuracy assessed by rigorous statistical methodology through ROC (receiver operating characteristics):

  • Area under the curve → test diagnostic accuracy
    • AUC (area under the curve): calculated with 95% confidence intervals and p values, for probability that an imaging measure was of greater diagnostic value than chance alone; 2-tailed $P<0.05$ significant

  • Youden index → test clinical predictive value*
    • Youden index: Maximize the sensitivity and specificity of the test to attain an ideal cutoff value at which the test has the greatest likelihood of correct prediction of outcome with best tradeoff of sensitivity and specificity

* Clinically meaningful improvement defined as $\text{rVCSS} > 4$-point ↓ from baseline to 6 months

VIDIO Trial - Baseline Characteristics

**Mean rVCSS**: 14.4 ± 5

<table>
<thead>
<tr>
<th>CEAP Stage</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEAP 4</td>
<td>50%</td>
</tr>
<tr>
<td>CEAP 5</td>
<td>33%</td>
</tr>
<tr>
<td>CEAP 6</td>
<td>17%</td>
</tr>
</tbody>
</table>

- **Nonthrombotic**: 45%
- **Post-thrombotic**: 20%
- **NO Lesion**: 35%

<table>
<thead>
<tr>
<th>Table II. Baseline demographics and lesion characteristics (VIDIO cohort, N = 100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
</tr>
<tr>
<td>Age, years</td>
</tr>
<tr>
<td>Male, No. (%)</td>
</tr>
<tr>
<td>White, No. (%)</td>
</tr>
<tr>
<td>Height, cm</td>
</tr>
<tr>
<td>Weight, kg</td>
</tr>
<tr>
<td>BMI</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Peripheral artery disease</td>
</tr>
<tr>
<td>Coronary artery disease</td>
</tr>
<tr>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>DVT in target limb</td>
</tr>
<tr>
<td>Taking anticoagulant medication</td>
</tr>
<tr>
<td>Taking antiplatelet medication</td>
</tr>
<tr>
<td>Lesion characteristics, No. (%)</td>
</tr>
<tr>
<td>Left study leg</td>
</tr>
<tr>
<td>Right study leg</td>
</tr>
<tr>
<td><strong>Nonthrombotic</strong></td>
</tr>
<tr>
<td><strong>Post-thrombotic</strong></td>
</tr>
<tr>
<td><strong>No lesion</strong></td>
</tr>
<tr>
<td>Ulcer size</td>
</tr>
<tr>
<td>Area, cm²</td>
</tr>
<tr>
<td>Maximum cranial-caudal dimension, cm</td>
</tr>
<tr>
<td>Maximum medial-lateral dimension, cm</td>
</tr>
</tbody>
</table>
VIDIO Trial - Baseline %DS Assessment

- MPV missed 26% of >50% DS lesions
- MPV underestimates the degree of %DS vs. IVUS
VIDIO Trial - Procedural Decision Making

IVUS changed Treatment plan in 57 of 100 subjects compared to Multiplanar Venogram

Treatment plan change distribution across 57 patients:

- 41, 72% from intention-NOT-to-treat to treatment
- 13, 23% from intention-to-treat to treatment
- 3, 5% from intention-to-treat to NO-treatment
- change in N of Stents
VIDIO Trial - 6-month Clinical Outcomes

Significant clinical improvement* @ 6-month in the stented patients

* >4-point ↓ in rVCSS
VIDIO Trial - 6-month Clinical Predictive Value

Use of IVUS significantly predicts clinical improvement if:

- baseline area stenosis >54% (Post and Non Thrombotic)
- baseline diameter stenosis >61% (non-thrombotic); Higher predictive value
- reduction of area stenosis >41% (from baseline to post-stent)

Conversely MPV of baseline stenosis and stenosis change are not predictive of 6-month clinical improvement
Conclusions

• VIDIO: Prospective, non-randomized, core-lab adjudicated study of imaging modalities to diagnose Ilio-femoral vein stenosis treatable in the proper clinical scenario with venous stenting; first and only rigorous comparison

• IVUS carries a significant superior diagnostic accuracy vs MPV translating into change in treatment in 57% of cases

• IVUS, but not MPV, carries a statistically significant clinical predictive value based on specific baseline (% diameter and area stenosis) and procedural (% area stenosis reduction) cut-off points, predictors of clinical improvement at 6 months

• Use of IVUS in iliofemoral vein obstruction changes treatment decision-making and potentially improves outcomes compared to MPV
THANK YOU!
VIDIO Trial - Baseline Patient Assessment

- IVUS diagnosed more patients & limbs with >50% degree of stenosis vs. MPV
- IVUS area and diameter measurements are concordant and consistently different vs. MPV measurements

DS = diameter stenosis
CSA = cross sectional area

**N of Patients with >50% degree of stenosis**

- IVUS (CSA >50%) = 49
- IVUS (DS >50%) = 47
- MPV (DS >50%) = 32
The VIDIO Trial: Diagnostic and Clinical Implications on the Use of IVUS for Deep Vein Treatment

Paul J. Gagne, MD, FACS, RVT
Chief, Vascular Surgery, Norwalk Hospital
Associate Clinical Professor of Surgery, NYU