Elevated Post-Intervention Villalta Scores Predict Late Post-Thrombotic Syndrome

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Disclosure

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I have the following potential conflicts of interest to report:

☑ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Can early Villalta scores be predictive of long-term PTS?

- Post thrombotic syndrome (PTS) is a common and debilitating complication of deep vein thrombosis (DVT)
- Khan et al. 2008 observed that 30-day Villalta score category was a strong predictor of later disease severity in DVT patients treated with anticoagulation (AC)\(^1\)
- There is no literature demonstrating the predictive ability of early Villalta scores in patients receiving interventional treatment

**Objective:** To determine if 30-day Villalta scores are associated with disease severity at later time points using patients from both CLOUT and ATTRACT.

Methods

Who
- Full unilateral CLOUT and ATTRACT populations with 30/180-day Villalta score data

What
- Logistic regression of 30-day Villalta scores to predict
  - PTS (5+)
  - Moderate/severe PTS (10+)
- At 6 and 12 months

How
- Measured with AUC and odds ratios

Excluded (N=377)
- Bilateral disease (N=22)
- Missing 30/180-day Villalta data (N=366)

\[\text{Evaluable Population} \quad N=814\]

CLOUT (MT) N=499

ATTRACT (PCDT) N=336

ATTRACT (AC) N=355

MT N=268

PCDT N=278

AC N=268

AC = anticoagulation, DVT = deep vein thrombosis, MT = mechanical thrombectomy, PCDT = pharmacomechanical catheter-directed thrombolysis.

Data sources: CLOUT registry data provided by study sponsor; ATTRACT study data made available under an NHLBI RMDA
Baseline characteristics
Combined cohort represents a variety of symptom durations, DVT locations, and types of treatment

<table>
<thead>
<tr>
<th></th>
<th>MT  N=268</th>
<th>PCDT N=278</th>
<th>AC  N=268</th>
<th>Combined N=814</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptom duration, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;7 days</td>
<td>N=263</td>
<td>N=277</td>
<td>N=268</td>
<td>N=808</td>
</tr>
<tr>
<td></td>
<td>129 (49.0%)</td>
<td>147 (53.1%)</td>
<td>130 (48.5%)</td>
<td>406 (50.2%)</td>
</tr>
<tr>
<td></td>
<td>64 (24.3%)</td>
<td>117 (42.2%)</td>
<td>121 (45.1%)</td>
<td>302 (37.4%)</td>
</tr>
<tr>
<td></td>
<td>70 (26.6%)</td>
<td>13 (4.7%)</td>
<td>17 (6.3%)</td>
<td>100 (12.4%)</td>
</tr>
<tr>
<td>7 to 14 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>&gt;14 days</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>DVT location, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iliofemoral</td>
<td>N=241</td>
<td>N=278</td>
<td>N=268</td>
<td>N=787</td>
</tr>
<tr>
<td></td>
<td>198 (82.2%)</td>
<td>159 (57.2%)</td>
<td>141 (52.6%)</td>
<td>498 (63.3%)</td>
</tr>
<tr>
<td></td>
<td>43 (17.8%)</td>
<td>119 (42.8%)</td>
<td>127 (47.4%)</td>
<td>289 (36.7%)</td>
</tr>
<tr>
<td>Isolated femoral-popliteal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Villalta score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>N=238</td>
<td>N=278</td>
<td>N=268</td>
<td>N=784</td>
</tr>
<tr>
<td></td>
<td>9.8 (5.8)</td>
<td>9.8 (5.1)</td>
<td>9.8 (5.7)</td>
<td>9.8 (5.5)</td>
</tr>
<tr>
<td>0–4 (%)</td>
<td>42 (17.6%)</td>
<td>43 (15.5%)</td>
<td>50 (18.7%)</td>
<td>135 (17.2%)</td>
</tr>
<tr>
<td>5–9 (%)</td>
<td>84 (35.3%)</td>
<td>100 (36.0%)</td>
<td>94 (35.1%)</td>
<td>278 (35.5%)</td>
</tr>
<tr>
<td>10–14 (%)</td>
<td>57 (23.9%)</td>
<td>82 (29.5%)</td>
<td>77 (28.7%)</td>
<td>216 (27.6%)</td>
</tr>
<tr>
<td>≥ 15 (%)</td>
<td>55 (23.1%)</td>
<td>53 (19.1%)</td>
<td>47 (17.5%)</td>
<td>155 (19.8%)</td>
</tr>
</tbody>
</table>

AC = anticoagulation, DVT = deep vein thrombosis, MT = mechanical thrombectomy, PCDT = pharmacomechanical catheter-directed thrombolysis.

1Any clot present in external iliac, common iliac, or common femoral vein.
30-day Villalta score prediction of any PTS
30-day Villalta scores predicted any PTS in all groups through 12 months

<table>
<thead>
<tr>
<th></th>
<th>AUC for 6 Months</th>
<th>Odds Ratio</th>
<th>AUC for 12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>MT</td>
<td>0.78</td>
<td>1.37*</td>
<td>0.66</td>
</tr>
<tr>
<td>PCDT</td>
<td>0.82</td>
<td>1.36*</td>
<td>0.77</td>
</tr>
<tr>
<td>AC</td>
<td>0.77</td>
<td>1.29*</td>
<td>0.76</td>
</tr>
<tr>
<td>Combined</td>
<td>0.79</td>
<td>1.34*</td>
<td>0.75</td>
</tr>
</tbody>
</table>

*P<0.0001

6 Months 12 Months

Odds Ratio AUC for 6 Months AUC for 12 Months
30-day Villalta score prediction of moderate/severe PTS

30-day Villalta scores predicted moderate/severe PTS in all groups through 12 months.

AUC for 6 Months

- MT: 0.81
- PCDT: 0.89
- AC: 0.80
- Combined: 0.84

AUC for 12 Months

- MT: 0.74
- PCDT: 0.90
- AC: 0.85
- Combined: 0.85

Odds Ratio

- 6 Months
  - MT: 1.34* (P<0.0001)
  - PCDT: 1.24* (P<0.0001)
  - AC: 1.30* (P<0.0001)
  - Combined: 1.30* (P<0.0001)

- 12 Months
  - MT: 1.46* (P<0.0001)
  - PCDT: 1.31* (P<0.0001)
  - AC: 1.33* (P<0.0001)
  - Combined: 1.33* (P<0.0001)
Conclusions

• 30-day Villalta scores can predict the likely trajectory of PTS across a variety of patients and treatments
  › Predictions are especially accurate for moderate/severe disease

• Application of these results may inform clinical expectations and influence future trial design
DEFIANCE | Now enrolling | NCT05701917
RCT of ClotTriever vs. anticoagulation in deep vein thrombosis

300 PATIENTS IN RCT: 1:1
Enrolling up to 300 patients with symptomatic proximal DVT, randomizing to intervention led by ClotTriever or conservative medical therapy alone.

PRIMARY ENDPOINT
Win ratio hierarchy comparing:
1. Occurrence of treatment failure or therapy escalation
2. Assessment of PTS severity, as defined by the Villalta scale, at the 6-month visit

FOLLOW UP
Patient followed through 6-months follow-up

ELIGIBLE PATIENTS:
Symptomatic unilateral iliofemoral DVT

300 Patient Randomized 1:1

ClotTriever Intervention Arm
Conservative Medical Management (Anticoagulation) Arm

Randomization (+/- Index Procedure) > 10-day Visit > 30-day Visit > 6-month Visit