Appropriate Use of Venous Imaging and Analysis of The D-Dimer/Clinical Probability Testing Paradigm In The Diagnosis And Location of Deep Venous Thrombosis

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VEITH Annual Symposium the 45th

Background

• Each year, DVT affects 900,000 in the US
• How to diagnose DVT:
  - Clinical exam
  - Wells Criteria score
  - D-Dimer (DD) level
  - Venous Duplex Ultrasound (VDU)

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Objective

• Primary objective was to determine if the combination of DD and Wells clinical probability could safely exclude DVT.
• Secondary objective was to determine if DD values could accurately predict magnitude and location of DVT.

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Are we using D-Dimer Enough?

• Recent surveys indicate that D-dimer assays are often not used appropriately for the exclusion of VTE in clinical practice

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Is DD Sensitive?

• Studies have demonstrated DD to be a sensitive and accurate assay that correlates with presence and volume of thrombus
  – ELISA (94% sensitivity and 45% specificity),
  – Latex (89% and 55%)


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Disclosures

• None

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**Usefullness of D- Dimer**

- Negative D-dimer test by the rapid ELISA method is as diagnostically useful as a negative CT or a negative VDU in excluding PE and DVT


**Statistical Analysis**

- Receiver Operator Characteristic curve (ROC) was used to find cut-off points for DD to predict DVT.
- Sensitivity, specificity, positive and negative predictive values were used for comparing accuracy of cut-off points.
- A ‘p’ value of 0.05 or less was considered significant.

**Methods**

- Retrospective study conducted over 4 consecutive years, 2012-2015.
- 1909 patients with limb swelling were evaluated for DVT.
  - 239 patients (12.5%) were excluded due to:
    - serial repeat visits/follow ups
    - screened for surveillance
    - had a previous history of DVT/PE

**Demographics**

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>%</th>
<th>Avg. Age</th>
<th>Lower CI</th>
<th>Upper CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>739</td>
<td>44.3</td>
<td>61.6</td>
<td>46.5</td>
<td>77.5</td>
</tr>
<tr>
<td>Females</td>
<td>931</td>
<td>55.7</td>
<td>62.5</td>
<td>46.0</td>
<td>79.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Median value</th>
<th>25th</th>
<th>75th</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-Dimer</td>
<td>2.02</td>
<td>0.86 mg/L</td>
<td>4.3 mg/L</td>
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</table>

**Results**

<table>
<thead>
<tr>
<th></th>
<th>CP</th>
<th>D-Dimer</th>
<th>DVT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>839</td>
<td>50.2</td>
<td>115</td>
<td>13.7</td>
</tr>
<tr>
<td>Moderate</td>
<td>752</td>
<td>45.0</td>
<td>79</td>
<td>10.5</td>
</tr>
<tr>
<td>High</td>
<td>79</td>
<td>4.7</td>
<td>8</td>
<td>10.1</td>
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<tr>
<td>P-value</td>
<td>0.127</td>
<td></td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1670</td>
<td>100.0</td>
<td>202</td>
<td>124.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>CP</th>
<th>D-Dimer</th>
<th>No DVT</th>
<th>Proximal</th>
<th>Distal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>0.1 - 0.59 (mg/L)</td>
<td>48</td>
<td>94.1</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>51</td>
</tr>
<tr>
<td>0.60-1.2 (mg/L)</td>
<td>48</td>
<td>94.1</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>51</td>
</tr>
<tr>
<td>≥ 1.3 (mg/L)</td>
<td>100</td>
<td>80.0</td>
<td>18</td>
<td>14.4</td>
<td>7</td>
<td>5.6</td>
</tr>
<tr>
<td>Total</td>
<td>174</td>
<td>86.1</td>
<td>18</td>
<td>8.9</td>
<td>10</td>
<td>5.0</td>
</tr>
</tbody>
</table>

P= 0.007
Results

- **26/202** DD values were in the normal range 0.1-0.59 mg/L, all negative for DVT (100% sensitive).
- **51/202** DD values were slightly elevated from 0.6-1.2 mg/L, only 3 DVTs were recorded, all of them Distal.
- **685** Patients with Wells scores <1, no D-dimer, and negative for DVT
- **Thus 762 patients of the sample data did not need to be sent for a stat VDU, but could have instead been treated on an outpatient basis.**

Testing Cost for 762 Patients

- **Cost of 762 ultrasounds:** $1,186,434.00
- **Cost of 762 DD tests:** $138,684.00
- **Potential savings over 8 months include at least $1,047,750.00**

Conclusion

- **DD is being under-utilized in patients suspected of having DVT.**
- **Patients with low or moderate clinical suspicion for DVT, should receive DD.**
- **Elevated DD >1.2 mg/L raises concern not only about presence but also about the volume and proximity of DVT.**
- **Our findings can be used to reduce unnecessary VDU testing and cost to patients and hospitals.**