Diaskintest

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Diaskintest (DST)

- A skin test using CFP10-ESAT6, produced by Echerichia coli BL21(DE3)/pCFP-ESAT.
- Manufactured by Generium in Russia.
- Since 2009, more than 20 million tests have been performed in Russia, Kazakhstan, Ukraine, Belarus, Kirgizstan, and Turkmenistan.

Literature review of Diaskintest

- **Database:**
  - Pubmed, Global Health Library, google scholar, and google.
  - UNION and ERS conference abstracts in the past 5 years.
- **Pubmed:** 7 articles in Russian.
- 14 abstracts at the ERS congress and 5 at the UNION.
- 3 English articles published in non-Medline journals.

  Starshinova et al. International Journal of Medical Sciences and Biotechnology. 2013; 1(5); 38-45
  Yablonsky et al. International Journal of Biomedicine. 2012; 2(3); 204-210
  Pavlova et al. Online International Interdisciplinary Research Journal, 2014; 4(5); 7-13
Comparison with TST (1)

249 children (3-14 yrs) between 2009-2011 in Russia. (BCG coverage >90%)

Children with active TB

Healthy children

Sensitivity: 93.4% vs 80%
Specificity: 20% vs 59%

Higher specificity than TST

Korneva et al. ERS congress 2013
Comparison with TST (2)

- 1,260,389 children and 169,658 adolescents tested by TST for mass screening in Russia.
- BCG coverage >90%

DST positive in only 3% of TST-positives who were BCG vaccinated

Slogotskaya et al. ERS congress 2016
159 BCG-vaccinated children (2-14 yrs) with a positive TST result.

<table>
<thead>
<tr>
<th>T-SPOT</th>
<th>Diaskintest</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negative (n=128)</td>
</tr>
<tr>
<td>Negative (n=148)</td>
<td>128</td>
</tr>
<tr>
<td>Indeterminate (n=2)</td>
<td>0</td>
</tr>
<tr>
<td>Positive (n=9)</td>
<td>0</td>
</tr>
</tbody>
</table>

Concordance rate: 87%; Kappa: 0.454 (95%CI: 0.274-0.634)

High concordance rate compared with T-SPOT
Comparison with IGRA (QFT-Gold) (1)

- 77 BCG-vaccinated children (3-14 yrs) tested by TST in Russia

**Similar reaction pattern compared with QFT-Gold**

Starshinova et al. ERS congress 2013
Comparison with IGRA (QFT-Gold) (2)

- 120 BCG-vaccinated Children (3-14 yrs).
- Children were sent for investigation due to a positive TST (n=80), contact with TB (n=35), and clinical complaint (n=5).

<table>
<thead>
<tr>
<th>QFT-Gold</th>
<th>Diaskintest</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negative (n=58)</td>
</tr>
<tr>
<td>Negative (n=69)</td>
<td>57</td>
</tr>
<tr>
<td>Indeterminate (n=1)</td>
<td>0</td>
</tr>
<tr>
<td>Positive (n=50)</td>
<td>1</td>
</tr>
</tbody>
</table>

Concordance rate: 88%; Kappa: 0.779 (95%CI: 0.676-0.881)

High concordance rate compared QFT-Gold
Performance of Diaskintest in patients with HIV

- 88 patients with HIV-associated TB
  - Diaskintest positive: 60.2% (mean CD4: DST + 392; DST-195)
    - Slogotskaya et al, ERS congress 2013

- 257 TB patients including 42 PLHIV
  - Diaskintest positive: 78.1% in HIV- and 52.4% in HIV+
    - Pnakratova et al, ERS congress 2013

Lower sensitivity in people living with HIV with lower CD4 counts
Predictive performance for development of active TB

- 80 children (3-14 yrs) diagnosed with LTBI by a positive TST result and chest CT findings (criteria not defined) in St. Petersburg, Russia. Followed up for 12 months.
- 32 (37.3%) received INH+PZA for 3 months.

<table>
<thead>
<tr>
<th>DST reaction size</th>
<th>Incident TB</th>
<th>Risk ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10mm</td>
<td>3/11 (27.3%)</td>
<td>Reference</td>
</tr>
<tr>
<td>10-14mm</td>
<td>15/24 (62.5%)</td>
<td>2.3 (0.83-6.3)</td>
</tr>
<tr>
<td>&gt;=15mm</td>
<td>33/45 (78.6%)</td>
<td>2.7 (1.0-7.2)</td>
</tr>
</tbody>
</table>

2 times higher risk of developing active TB in DST positives compared to negatives

Korneva et al. ERS congress 2015
Correlation with disease activity?

**DST positive rate in pulmonary TB patients**

<table>
<thead>
<tr>
<th>N</th>
<th>Treatment duration (days)</th>
<th>Positive Diaskintest reaction</th>
<th>n</th>
<th>%</th>
<th>95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>497</td>
<td>1-30</td>
<td></td>
<td>425</td>
<td>85,1</td>
<td>82,1-88,4</td>
</tr>
<tr>
<td>112</td>
<td>100-120</td>
<td></td>
<td>61</td>
<td>54,5</td>
<td>45,2-63,4</td>
</tr>
<tr>
<td>595</td>
<td>1 year after completed</td>
<td></td>
<td>61</td>
<td>10,3</td>
<td>8,1-13,0</td>
</tr>
<tr>
<td></td>
<td>treatment</td>
<td></td>
<td></td>
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</tbody>
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Lower DST positive rate in those who have completed TB treatment

Slogotskaya et al, ERS congress 2013
Conclusions

- Very limited data reported in English literature and most data are among children and adolescents.

- Diaskintest appears to have higher specificity than TST and similar performance to IGRA in BCG-vaccinated children.