NAVIGATING THE DIAGNOSTIC GREYZONE WITH tCEC

TUMOR-DERIVED CIRCULATING ENDOTHELIAL CELLS (tCEC) PREDICT CLINICALLY SIGNIFICANT PROSTATE CARCINOMA

S.C. BHAKDI1, P. SURYAPHOL3, P. THAICHAROEN2, B. CHAIYAPRASITHI4 & K. CHARNKAEW5

Department of Pathobiology, Mahidol University, Thailand | 1Division of Pathobiology, Siriraj Hospital, Mahidol University, Thailand | 2Department of Urology, Division of Urology, Department of Surgery, Faculty of Medicine, Mahidol University, Thailand | 3Division of Pathology, Faculty of Medicine, Siriraj Hospital, Mahidol University, Thailand | 4Department of Pathobiology, Faculty of Medicine, Siriraj Hospital, Mahidol University, Thailand

OBJECTIVE
Assess the predictive value of tumor-derived Circulating Endothelial Cells (tCEC) for the presence of prostate cancer (PCa) on tissue biopsy.

METHODS
Prospective single-centre setting
- 142 patients with PSA values below/within/above the diagnostic grey zone of 4-10ng/mL
- Collected blood samples prior to first prostate tissue biopsy
- Negative cell isolation: erythrocyte lysis & hMX™ magnetic depletion of leukocytes (X-ZELL)
- Cryoimmunostaining™ (X-ZELL) & microscopic analysis for tCEC detection

RESULTS (DATA)
Multiply PPV & increase high NPV for 69 patients below & within the diagnostic grey zone:

Clin. significant cancers (csPCa):

<table>
<thead>
<tr>
<th>ppv</th>
<th>NPV</th>
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<tbody>
<tr>
<td>PSA only</td>
<td>9.5%</td>
</tr>
<tr>
<td>PSA with tCEC</td>
<td>20.7%</td>
</tr>
</tbody>
</table>

All prostate cancers (PCa):

<table>
<thead>
<tr>
<th>ppv</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA only</td>
<td>34.9%</td>
</tr>
<tr>
<td>PSA with tCEC</td>
<td>55.2%</td>
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CONCLUSION
Adding tCEC detection below & within the diagnostic grey zone can:
- BOOST the predictive value of PSA &
- REDUCE unnecessary prostate biopsies

Dr. Sebastián C.P. Bhakdi
Department of Pathobiology, Faculty of Science, Mahidol University, Bangkok, 10400, Thailand

REFERENCES

Dr. Sebastián C.P. Bhakdi
Department of Pathobiology, Faculty of Science, Mahidol University, Bangkok, 10400, Thailand

Diagnosis of prostate cancer patients (2017) isolated from cubital blood drawn from prostate biopsy. Stained using T-ZELL Cryoimmunostaining™

WHAT ARE tCEC?1-4
- Shed directly from tumour’s own blood vessels
- Characterised by complete absence of cancer cell surface markers
- Carry many common blood cell markers (thus hard to find in routine)
- Shed from earliest stage tumours less than 1mm in size
- Presence may indicate if cancer is likely to cause harm

DIAGNOSTIC GREYZONE: PROCEEDING UNCLEAR!

Clinical net benefit of added tCEC biopsies (71.7%)
Could have avoided 39 unnecessary prostate biopsies (20.7% PPV = x2.2 MULTIPLIED INCREASE NPV to 95%)

CLIN. NET BENEFIT: 71.1% OF UNNECESSARY BIOPSIES AVOIDED