Testing patterns and predictive value of Prostate Specific Antigen in a European HIV – positive cohort: Does one size fit all?

L Shepherd, A Borges, L Ravn, R Harvey, M Bower, A Grulich, M Silverberg, Ole Kirk, J Lundgren, A Mocroft on behalf of EuroSIDA in EuroCOORD
Background

• cART has improved survival of HIV+ people and the proportion living past 50 is increasing

• Cancers associated with older age, such as prostate cancer, are expected to become more prevalent

• Prostate specific antigen (PSA) is a protein associated with higher prostate cancer risk
Background

• There is limited data available on variations in PSA testing practices in HIV+ men

• No clear guidelines on use of PSA tests in HIV+ men, which largely rely on application of recommendations for the general population (PSA>4 ug/L)
Aims

• To describe variations in PSA testing patterns in European HIV+ men
  Cohort study in EuroSIDA

• To assess the use of PSA>4 µg/L to indicate PCa risk and to identify whether a better cut-off exists for HIV positive people
  nested case-control study in EuroSIDA
1. Variations in PSA testing in HIV+ men across Europe
PSA testing rates in Europe

Cohort study

PCa free at baseline

Baseline: Latest of first visit or 1 Jan 2008

Centres screening ≥ 5% of men per year

Followed until first PCa diagnosis, last visit or death
## PSA testing rates: Baseline characteristics

<table>
<thead>
<tr>
<th>Baseline N(%)/Median (IQR)</th>
<th>All Men</th>
<th>≥1 PSA test</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall</strong></td>
<td>4,482 (100)</td>
<td>1,318 (100)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>41 (35,48)</td>
<td>44 (38,52)</td>
</tr>
<tr>
<td><strong>Region</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>East</td>
<td>694 (15)</td>
<td>302 (23)</td>
</tr>
<tr>
<td>Argentina</td>
<td>262 (6)</td>
<td>27 (2)</td>
</tr>
<tr>
<td>South</td>
<td>1,389 (31)</td>
<td>393 (30)</td>
</tr>
<tr>
<td>West</td>
<td>814 (18)</td>
<td>284 (22)</td>
</tr>
<tr>
<td>North</td>
<td>1,323 (30)</td>
<td>312 (24)</td>
</tr>
<tr>
<td><strong>Risk group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homosexual</td>
<td>2,701 (60)</td>
<td>860 (65)</td>
</tr>
<tr>
<td>Heterosexual</td>
<td>561 (13)</td>
<td>141 (11)</td>
</tr>
<tr>
<td>IDU</td>
<td>925 (21)</td>
<td>242 (18)</td>
</tr>
<tr>
<td><strong>Non-white ethnicity</strong></td>
<td>348 (8)</td>
<td>78 (6)</td>
</tr>
<tr>
<td>Prior AIDS event</td>
<td>1,202 (27)</td>
<td>413 (31)</td>
</tr>
<tr>
<td>Prior Non-AIDS event*</td>
<td>198 (4)</td>
<td>66 (5)</td>
</tr>
<tr>
<td>Prior ART</td>
<td>3,917 (87)</td>
<td>1,205 (91)</td>
</tr>
<tr>
<td>CD4 cells/mm$^3$</td>
<td>510 (360,702)</td>
<td>519 (368,720)</td>
</tr>
<tr>
<td>HIV-viral load copies/ml</td>
<td>&lt;49 (&lt;39,&lt;59)</td>
<td>&lt;49 (&lt;39,&lt;49)</td>
</tr>
</tbody>
</table>

*Non-AIDS defining events: pancreatitis, grade 3 or 4 hepatic encephalopathy or liver-related death, myocardial infarction, stroke, coronary artery bypass graft, coronary angioplasty, carotid endarterectomy (grouped together as serious CV events), and end-stage renal disease.
Adjusted incidence rate ratios of receiving PSA testing during follow-up after 1/1/2008

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>0.4</th>
<th>0.8</th>
<th>1.6</th>
<th>3.2</th>
<th>6.4</th>
<th>12.8</th>
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<tbody>
<tr>
<td>&lt; = 35</td>
<td></td>
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<tr>
<td>36 - 40</td>
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<td>41 - 50</td>
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<tr>
<td>51 +</td>
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</table>

<table>
<thead>
<tr>
<th>Calendar year (per 5 years additional follow-up)</th>
<th>0.4</th>
<th>0.8</th>
<th>1.6</th>
<th>3.2</th>
<th>6.4</th>
<th>12.8</th>
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<tbody>
<tr>
<td>East central</td>
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<td>East</td>
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<td>South</td>
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<td>West</td>
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<tr>
<td>North (Reference)</td>
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</table>

<table>
<thead>
<tr>
<th>Region</th>
<th>0.4</th>
<th>0.8</th>
<th>1.6</th>
<th>3.2</th>
<th>6.4</th>
<th>12.8</th>
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<td>North (Reference)</td>
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<table>
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<tr>
<th>Risk group</th>
<th>0.4</th>
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<th>1.6</th>
<th>3.2</th>
<th>6.4</th>
<th>12.8</th>
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<tr>
<td>Homosexual (Reference)</td>
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<tr>
<td>IDU</td>
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<tr>
<td>Heterosexual</td>
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<table>
<thead>
<tr>
<th>Non-white vs White ethnicity</th>
<th>0.4</th>
<th>0.8</th>
<th>1.6</th>
<th>3.2</th>
<th>6.4</th>
<th>12.8</th>
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<table>
<thead>
<tr>
<th>Smoking status</th>
<th>0.4</th>
<th>0.8</th>
<th>1.6</th>
<th>3.2</th>
<th>6.4</th>
<th>12.8</th>
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</thead>
<tbody>
<tr>
<td>Never (reference)</td>
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<tr>
<td>Current</td>
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<tr>
<td>Former</td>
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</table>

<table>
<thead>
<tr>
<th>Hepatitis C + (Yes vs No)</th>
<th>0.4</th>
<th>0.8</th>
<th>1.6</th>
<th>3.2</th>
<th>6.4</th>
<th>12.8</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>CD4 count/mm³</th>
<th>0.4</th>
<th>0.8</th>
<th>1.6</th>
<th>3.2</th>
<th>6.4</th>
<th>12.8</th>
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<tr>
<td>0 - &lt;200</td>
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<tr>
<td>200 - &lt; 350</td>
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<tr>
<td>350 - &lt; 500</td>
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<tr>
<td>500 + (Reference)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>HIV VL &gt; 400 vs ≤ 400 cps/mL²</th>
<th>0.4</th>
<th>0.8</th>
<th>1.6</th>
<th>3.2</th>
<th>6.4</th>
<th>12.8</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Prior ART vs None</th>
<th>0.4</th>
<th>0.8</th>
<th>1.6</th>
<th>3.2</th>
<th>6.4</th>
<th>12.8</th>
</tr>
</thead>
</table>

Models additionally adjusted for:
Ethnic origin, BMI at baseline, and time-updated diagnoses of AIDS defining and non-AIDS malignancies [ADM], NADM, AIDS-defining [excluding ADM], and non-AIDS-defining events [defined as cardiovascular, end-stage renal disease, liver failure and pancreatitis, excluding NADM], prior hypertension, prior and hepatitis-B infection.
Adjusted incidence rate ratios of receiving PSA testing during follow-up after 1/1/2008

Age (Years)
- <= 35
- 36 - 40 (Reference)
- 41 - 50
- 51 +

Calendar year (per 5 years additional follow-up)

Region
- East central
- East
- Argentina
- South
- West
- North (Reference)

Risk group
- Homosexual (Reference)
- IDU
- Heterosexual

Non-white vs White ethnicity

Smoking status
- Never (reference)
- Current
- Former

Hepatitis C + (Yes vs No)

CD4 count/mm³
- 0 -<200
- 200 - < 350
- 350 - < 500
- 500 + (Reference)

HIV VL > 400 vs ≤ 400 cps/mL²

Prior ART vs None

Models additionally adjusted for:
- Ethnic origin, BMI at baseline, and time-updated diagnoses of AIDS defining and non-AIDS malignancies [ADM], NADM, AIDS-defining [excluding ADM], and non-AIDS-defining events [defined as cardiovascular, end-stage renal disease, liver failure and pancreatitis, excluding NADM], prior hypertension, prior and hepatitis-B infection
Adjusted incidence rate ratios of receiving PSA testing during follow-up after 1/1/2008

Models additionally adjusted for:
Ethnic origin, BMI at baseline, and time-updated diagnoses of AIDS defining and non-AIDS malignancies [ADM], NADM, AIDS-defining [excluding ADM], and non-AIDS-defining events [defined as cardiovascular, end-stage renal disease, liver failure and pancreatitis, excluding NADM], prior hypertension, prior and hepatitis-B infection

Age (Years)
- <= 35
- 36 - 40 (Reference)
- 41 - 50
- 51 +

Calendar year (per 5 years additional follow-up)

Region
- East central
- East
- Argentina
- South
- West
- North (Reference)

Risk group
- Homosexual (Reference)
- IDU
- Heterosexual

Non-white vs White ethnicity

Smoking status
- Never (reference)
- Current
- Former

Hepatitis C + (Yes vs No)

CD4 count/mm$^3$
- 0 - <200
- 200 - < 350
- 350 - < 500
- 500 + (Reference)

HIV VL > 400 vs ≤ 400 cps/mL$^2$

Prior ART vs None

Adjusted incidence rate ratios (IRR) with 95% confidence intervals (95%CI)
Adjusted incidence rate ratios of receiving PSA testing during follow-up after 1/1/2008

Age (Years)
- <= 35
- 36 - 40 (Reference)
- 41 - 50
- 51 +

Calendar year (per 5 years additional follow-up)

Region
- East central
- East
- Argentina
- South
- West
- North (Reference)

Risk group
- Homosexual (Reference)
- IDU
- Heterosexual

Non-white vs White ethnicity

Smoking status
- Never (reference)
- Current
- Former

Hepatitis C + (Yes vs No)

CD4 count/mm$^3$
- 0 -<200
- 200 -< 350
- 350 -< 500
- 500 + (Reference)

HIV VL > 400 vs ≤ 400 cps/mL$^2$

Prior ART vs None

Models additionally adjusted for:
Ethnic origin, BMI at baseline, and time-updated diagnoses of AIDS defining and non-AIDS malignancies [ADM], NADM, AIDS-defining [excluding ADM], and non-AIDS-defining events [defined as cardiovascular, end-stage renal disease, liver failure and pancreatitis, excluding NADM], prior hypertension, prior and hepatitis-B infection

EuroSida

EuroCoord
Adjusted incidence rate ratios of receiving PSA testing during follow-up after 1/1/2008

- **Age (Years)**
  - ≤ 35
  - 36 - 40 (Reference)
  - 41 - 50
  - 51 +

- **Calendar year (per 5 years additional follow-up)**

- **Region**
  - East central
  - East
  - Argentina
  - South
  - West
  - North (Reference)

- **Risk group**
  - Homosexual (Reference)
  - IDU
  - Heterosexual

- **Non-white vs White ethnicity**

- **Smoking status**
  - Never (reference)
  - Current
  - Former

- **Hepatitis C + (Yes vs No)**

- **CD4 count/mm³**
  - 0 -<200
  - 200 - < 350
  - 350 - < 500
  - 500 + (Reference)

- **HIV VL > 400 vs ≤ 400 cps/mL²**

- **Prior ART vs None**

Models additionally adjusted for:
Ethnic origin, BMI at baseline, and time-updated diagnoses of AIDS defining and non-AIDS malignancies [ADM], NADM, AIDS-defining [excluding ADM], and non-AIDS-defining events [defined as cardiovascular, end-stage renal disease, liver failure and pancreatitis, excluding NADM], prior hypertension, prior and hepatitis-B infection
Adjusted incidence rate ratios of receiving PSA testing during follow-up after 1/1/2008

Models additionally adjusted for: Ethnic origin, BMI at baseline, and time-updated diagnoses of AIDS defining and non-AIDS malignancies [ADM], NADM, AIDS-defining [excluding ADM], and non-AIDS-defining events [defined as cardiovascular, end-stage renal disease, liver failure and pancreatitis, excluding NADM], prior hypertension, prior and hepatitis-B infection
2. To assess the use of PSA > 4 µg/L to indicate PCa risk and to identify whether a better cut-off exists for HIV positive people
Optimal PSA cut off

Nested case control study
Optimal PSA cut off

Nested case control study

Cases

Prostate cancer

After 1 Jan 2001

Prior plasma sample
Optimal PSA cut off

Nested case control study

Cases/ Controls

No prostate cancer

After 1 Jan 2001

Prior plasma sample
Optimal PSA cut off

Nested case control study

Cases/controls

Matched

1\textsuperscript{st} sample date ± 2 years

Last sample date ± 2 years

Age (1\textsuperscript{st} sample) ± 10 years

CD4 (1\textsuperscript{st} sample) ± 200 cells/mm\textsuperscript{3}

Region of Europe
Optimal PSA cut off

Nested case control study

Cases/controls

Matched

Total PSA (tPSA)

Samples
Optimal PSA cut off

Nested case control study
Optimal PSA cut off

EuroSIDA
Men with follow-up >1 January 2001
9,112

Nested case control study

Controls
N=40

Prostate cancers
N=21
## Baseline Characteristics (first sample)

<table>
<thead>
<tr>
<th>Factors</th>
<th>Total</th>
<th>Prostate cancer</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>Cases</td>
<td>Controls</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>61 (100.0)</td>
<td>21 (100.0)</td>
<td>40 (100.0)</td>
</tr>
<tr>
<td><strong>Risk group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homosexual</td>
<td>47 (77.0)</td>
<td>17 (81.0)</td>
<td>30 (75.0)</td>
</tr>
<tr>
<td>Heterosexual</td>
<td>7 (11.5)</td>
<td>2 (9.5)</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td>IDU</td>
<td>2 (3.3)</td>
<td>0 (0.0)</td>
<td>2 (5.0)</td>
</tr>
<tr>
<td><strong>Non White ethnicity</strong></td>
<td>4 (6.6)</td>
<td>0 (0.0)</td>
<td>4 (10.0)</td>
</tr>
<tr>
<td><strong>Prior NADM</strong></td>
<td>2 (3.3)</td>
<td>2 (9.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Prior rADM</strong></td>
<td>6 (9.8)</td>
<td>0 (0.0)</td>
<td>6 (15.0)</td>
</tr>
<tr>
<td><strong>On cART</strong></td>
<td>58 (95.1)</td>
<td>20 (95.2)</td>
<td>38 (95.0)</td>
</tr>
<tr>
<td><strong>Median (IQR)</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Age</td>
<td>51 (48.57)</td>
<td>52 (49.57)</td>
<td>51 (47.56)</td>
</tr>
<tr>
<td>CD4 count (cells/mm$^3$)</td>
<td>437 (243,610)</td>
<td>460 (260,610)</td>
<td>426 (230,595)</td>
</tr>
<tr>
<td>$\log_{10}$ HIV VL (copies/ml)</td>
<td>1.9 (1.6,2.6)</td>
<td>1.9 (1.6,2.6)</td>
<td>2.0 (1.6,2.6)</td>
</tr>
</tbody>
</table>

**EuroSIDA**

**EuroCoord**
total PSA by time before diagnosis

Years before PCa/last sample

tPSA(µg/L)

Case  - ○
Control - △
Median latest total PSA in cases and controls

Case
Control
IQR

P=0.04
ROC curve and Area Under the Curve for total PSA

AUC=0.9
Optimal cut-off for total PSA
Sensitivity: 38%
Specificity: 99%

Optimal cut-off for total PSA
Sensitivity: 81%
Specificity: 84%

Optimal cut-off for total PSA
Optimal cut-off for total PSA

Sensitivity: 81%
Specificity: 84%
**Optimal cut-off for total PSA**

<table>
<thead>
<tr>
<th>Age group</th>
<th>Cut off</th>
<th>Range</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 50</td>
<td>1.4</td>
<td>1.2 – 2.8</td>
<td>86%</td>
<td>94%</td>
</tr>
</tbody>
</table>

**Sensitivity and specificity for total PSA**

Total PSA > 1.5 µg/L
Optimal cut-off for total PSA

<table>
<thead>
<tr>
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<td>86%</td>
<td>94%</td>
</tr>
<tr>
<td>≥50</td>
<td>1.5</td>
<td>-</td>
<td>81%</td>
<td>82%</td>
</tr>
</tbody>
</table>
Limitations

- PSA testing not reported by all centres and under reported
- Reason for PSA testing unknown
- Small number of prostate cancers
- Observational study
Conclusions

• PSA testing in HIV+ men varied in clinics across Europe, and was particularly high in older men

• Total PSA > 4µg/L to indicate high PCa risk was not sensitive in HIV+ men

• Use of the lower cut-off of PSA > 1.5µg/L should be considered

• Clear guidelines on the role of PSA in PCa screening and management for HIV+ men are needed
The EuroSIDA Study Group

The multi-centre study group, EuroSIDA (national coordinators in parenthesis).

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