Cost-effectiveness of SelectMDx for prostate cancer in four European Countries

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Background

- SelectMDx is a 2-gene qPCR urine test combining a biomarker expression profile with clinical risk factors and is used for the stratification of a patient's risk for having clinically significant prostate cancer (CS PCa) upon biopsy.
- Besides the diagnostic accuracy of the test, also the context of a specific country determines the health benefit and cost-effectiveness.
- We assessed the health benefit and cost-effectiveness of SelectMDx in France, Germany, Italy and Spain.

Methods

- We developed a decision analytical model to compare the current TRUS-Bx strategy with the SelectMDx strategy.
- The target population are men in France, Germany, Italy, and Spain who, under current guideline-concordant management, would undergo initial transrectal ultrasound prostate biopsy (TRUS-Bx).
- In the TRUS-Bx strategy the model classified men based upon the diagnostic outcome of TRUS-Bx with the subsequent probabilities of treatment.
- In the SelectMDx strategy, only patients with a positive SelectMDx test receive TRUS-Bx (see model structure) which can result in:
  - Prevention of biopsies in men without PCa.
  - Reduction of potential overdiagnosis and overtreatment of clinically insignificant prostate cancer (CI PCa).
  - The potential risk of missing some CS PCa in negative SelectMDx cases resulting in delayed treatment.
- Long-term consequences of the diagnostic outcomes on survival and quality of life were included in the model.
- Model input (current detection rates, treatment distributions, costs, diagnostic accuracy of SelectMDx, mortality and quality of life) was based on literature most relevant for a contemporary cohort of patients in each of the four countries.
- Expected costs and quality adjusted life years (QALYs) were calculated for both strategies in each of the four countries.

Results - diagnostic outcomes

- Using the model, diagnostic outcomes were assessed for each of the four countries. The Table shows the outcomes for Spain for 1000 patients and for the total target population in Spain (n=81,242).

<table>
<thead>
<tr>
<th>Strategy</th>
<th>SelectMDx tests</th>
<th>TRUS biopsies</th>
<th>Biopsy while no Pca</th>
<th>Detected CI PCa</th>
<th>Detected CS PCa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>0</td>
<td>1000</td>
<td>666</td>
<td>139</td>
<td>195</td>
</tr>
<tr>
<td>SelectMDx Strategy</td>
<td>1000</td>
<td>540</td>
<td>261</td>
<td>92</td>
<td>187</td>
</tr>
<tr>
<td>Difference per 1000 patients</td>
<td>+1000</td>
<td>-460</td>
<td>-405</td>
<td>-47</td>
<td>-8</td>
</tr>
<tr>
<td>Difference for population</td>
<td>+81,242</td>
<td>-37,363</td>
<td>-32,903</td>
<td>-3,784</td>
<td>-683</td>
</tr>
</tbody>
</table>

Conclusions

- Using SelectMDx reduces the number of biopsies and reduces the detection of insignificant PCa at the cost of missing some significant PCa.
- Missing insignificant PCa showed to be advantageous in the model, even when including a higher mortality for missed insignificant PCa.
- In all four countries the reduction of biopsies and reduction in detected insignificant cancers with the SelectMDx strategy outweighed the negative consequences of missing some significant PCa.
- SelectMDx resulted in health gain and cost savings in the initial diagnosis of PCa in all four countries. Prevention of overdiagnosis and overtreatment were the main factors in the beneficial outcomes.