Ivabradine’s added therapeutic and pharmaco-economic value in Portugal

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Summary

- Portuguese health system & financing
- Cost-effectiveness of ivabradine: supporting reimbursement
- Decision tool supporting the economic efficiency of ivabradine in the Portuguese NHS hospitals
- Discussion and conclusion
Pricing & reimbursement

• Agency: INFARMED (Regulatory; Pricing; HTA)
• Primary care drugs
  – Price (reference countries Spain, Italy and Slovenia)
  – HTA (added therapeutic value; economic value)
  – Reimbursement (15%, 37%, 69%, 90%)
• Hospital drugs
  – Mandatory therapeutic value and economic value assessment prior to utilization by NHS hospitals
  – several layers of decision until effective use
    • Central (HTA, budget caps, clinical guidelines, positive list)
    • Local (Pharmacy and Therapeutics Committee, financial agreements)
  – 100% public funding
Cardiovascular diseases/hearth failure in Portugal

• Cardiovascular diseases
  – 1\textsuperscript{st} cause of death in Portugal
  – 2\textsuperscript{nd} most frequent cause of hospitalization in NHS hospitals
  – 1\textsuperscript{st} Pharmacotherapeutic Group in NHS Expenditure (30% of ambulatory)
  – >15\textdegree Pharmacotherapeutic Group in NHS Expenditure (hospital)

• Heart failure
  – Most frequent CV hospitalization, DRG 127 in 2006 (n= 15,664, 16\% of all CV)
  – High 30 days, 6 months and 12 months readmission rate (7.8\%\textsuperscript{1}, 20.9\%\textsuperscript{2}, 23.9\%\textsuperscript{2})
  – High in-hospital mortality (5.5\%\textsuperscript{2}-17.3\%\textsuperscript{1})
  – No study on costs, however 50-75\% due to hospitalizations!

Cost-effectiveness of ivabradine: supporting reimbursement

Chronic heart failure NYHA II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥ 75 bpm

Markov modelling approach to extrapolate beyond clinical trial duration

Cost-effectiveness of ivabradine: supporting reimbursement

Median OS = 85 months  
Mean Life expectancy = 116.8 months

IVABRADINE
14 months increment in median OS  
18 months gain in Life expectancy

Median OS = 71 months  
Mean Life expectancy = 98.7 months

Ivabradine (Overall Survival)

Placebo (Overall Survival)
Cost-effectiveness of ivabradine: supporting reimbursement

<table>
<thead>
<tr>
<th></th>
<th>Ivabradine</th>
<th>Placebo</th>
<th>IVA vs PLA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Costs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>25 815,07 €</td>
<td>21 342,70 €</td>
<td>4 472,37 €</td>
</tr>
<tr>
<td>Ivabradine</td>
<td>5 303,65 €</td>
<td>0,00 €</td>
<td>5 303,65 €</td>
</tr>
<tr>
<td>other HF therapy</td>
<td>1 893,56 €</td>
<td>1 681,52 €</td>
<td>212,05 €</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>16 850,70 €</td>
<td>18 091,92 €</td>
<td>-1 241,22 €</td>
</tr>
<tr>
<td>Monitoring</td>
<td>1 767,16 €</td>
<td>1 569,27 €</td>
<td>197,89 €</td>
</tr>
<tr>
<td><strong>Effectiveness</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life Years</td>
<td>6,87 LY</td>
<td>6,10 LY</td>
<td>0,77 LY</td>
</tr>
<tr>
<td>QALY</td>
<td>5,15 QALY</td>
<td>4,50 QALY</td>
<td>0,65 QALY</td>
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</tbody>
</table>

ICER

Effectiveness

Ivabradine considered cost-effective at the commonly accepted ICER threshold (< 30,000€)

In UK NICE considered Ivabradine cost-effective at £8,498 per QALY

5% discount rate for costs and effectiveness
How to translate CE into economic efficiency at hospital level?

• NHS hospitals contracting system 2014
  – National objectives
    • Length of stay
    • Readmission within 30 days
  – Variable regional objectives

<table>
<thead>
<tr>
<th></th>
<th>Prices / Costs</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalization (price medical DRG)</td>
<td>2 120.28€</td>
<td>ACSS contrato programa 2014</td>
</tr>
<tr>
<td>Cardiology department daily cost</td>
<td>438€</td>
<td>BDEA 2008</td>
</tr>
<tr>
<td>Mean length of stay for heart failure</td>
<td>10,2 days</td>
<td></td>
</tr>
<tr>
<td>Hospitalization cost for cardiology department (BDEA 2008)</td>
<td>4 467 € (4.6% medicines)</td>
<td>BDEA 2008</td>
</tr>
<tr>
<td>% of patients without previous hospitalizations</td>
<td>15%</td>
<td>Cleland et al. European Heart Journal (2003)</td>
</tr>
</tbody>
</table>
Decision tool: economic efficiency of ivabradine in the Portuguese NHS hospitals

INPUT (hospital)
- Demographics
- Epidemiology
- Treatment
- Resource utilization

Outcomes (hospital)
- Epidemiology
- Therapeutic efficiency
- Economic efficiency
- Budget impact
Decision tool: economic efficiency of ivabradine in the Portuguese NHS hospitals

INPUT (hospital)

Demographics

Epidemiology

Treatment

Resource utilization

Population served by the hospital
Decision tool: economic efficiency of ivabradine in the Portuguese NHS hospitals

INPUT (hospital)
- Demographics
- Epidemiology
  - Heart failure prevalence
- Treatment
- Resource utilization
Decision tool: economic efficiency of ivabradine in the Portuguese NHS hospitals

INPUT (hospital)
- Demographics
- Epidemiology
- Treatment
- Resource utilization

With or without IVA
Shift clinical trial data
Endpoints (1yrs):
- CV death
- Admission for worsening HF
Decision tool: economic efficiency of ivabradine in the Portuguese NHS hospitals

INPUT (hospital)
- Demographics
- Epidemiology
- Treatment
- Resource utilization

Hospitalization
- Medicines
- Primary and secondary care
Decision tool: economic efficiency of ivabradine in the Portuguese NHS hospitals

- HF population
- Patients eligible for IVA treatment

- Outcomes (hospital)
- Epidemiology
  - Therapeutic efficiency
  - Economic efficiency
  - Budget impact
Decision tool: economic efficiency of ivabradine in the Portuguese NHS hospitals

- Events avoided (CV death and hospitalizations)
- Life years gained
- Outcomes (hospital)
- Epidemiology
- Therapeutic efficiency
- Economic efficiency
- Budget impact
Decision tool: economic efficiency of ivabradine in the Portuguese NHS hospitals

Outcomes (hospital)

Epidemiology

Therapeutic efficiency

Economic efficiency

Length of stay, visits...

Primary and secondary care costs

Budget impact
Decision tool: economic efficiency of ivabradine in the Portuguese NHS hospitals

- Outcomes (hospital)
- Epidemiology
- Therapeutic efficiency
- Economic efficiency
- Budget impact

- Expected number of patients to be treated
- Treatment costs by Segment
Ivabradine: 1 year results hospital perspective

**Therapeutic efficiency**

- Avoid 1 CV death: 52
- Avoid 1 admission for worsening HF: 19
- Avoid 1 CV death or 1 HF hospitalization: 17
- Gain 1 year of life: 3

**Economic efficiency**

1st year treatment costs

- Ivabradine: 501 €
- Acute phase hospitalization: -382 €
- Post hospitalization (3-6 mo): -223 €
- Net total cost: -104 €
Discussion and conclusion

• Pharmacoeconomics has an established role in pricing and reimbursement of medicines in Portugal

• Applied health economics/economic evaluation is increasingly important in supporting health care decisions

• Ivabradine was found to be a cost-effective treatment option in Portugal

• The use of ivabradine may contribute to reduce hospitals budget while enhancing health outcomes in patients with heart failure