Towards a better paradigm for breast cancer screening

Establishing risk based strategies and informing women and health professionals about benefits and harms

Rué M., Carles M., Sala M.
on behalf of the InforMa group
Outline

1. Re-designing screening for breast cancer

2. Systematic review on Decision Aids

3. Informing women about benefits and harms
Re-designing screening for breast cancer
Screening is evolving

- Tailored to the level of risk. Ongoing studies on screening for breast cancer:
  - WISDOM
  - PERSPECTIVE
  - ASSURE
  - ...

- Population provided with more extensive information on benefits and harms

- Re-defining what is cancer: L. Esserman
  - Old paradigm: inexorable progression
  - New paradigm: variable progression
Risk-based versus fixed strategies

Cost-Effectiveness and Harm-Benefit Analyses of Risk-Based Screening Strategies for Breast Cancer

Ester Vilaprinyo¹,²*, Carles Forné¹,²*, Misericordia Carles³, Maria Sala⁴,⁵, Roger Pla⁶,⁷, Xavier Castells⁴,⁵, Laia Domingo⁴, Montserrat Rue¹,²,⁵*, the Interval Cancer (INCA) Study Group⁵

• Reductions ≃ 10% in costs and 20-25% in false-positive results and overdiagnosed cases were obtained for risk-based strategies.

• Optimal screening is characterized by 5-year or 3-year periodicity for the low or moderate risk-groups and 1-year periodicity for the high-risk group.

Plos One 2014
| Re-designing screening for breast cancer | Systematic review on Decision Aids | Informing women about benefits and harms |
Systematic review of DAs

Records identified through database searching and screened in title or abstract (n=95)

- Records excluded (n=83)

Full-text articles assessed for eligibility (n=12)

- Full-text articles excluded (n=8):
  - Aimed to develop a decision aid (DA), but not assessed in real context (n=5)
  - Aimed to compare different formats of DA (n=1)
  - Aimed to compare different educational/ethnicity groups (n=1)
  - Pilot assessment of a DA (the final article is already included) (n=1)

Studies included in qualitative and quantitative synthesis (meta-analysis) (n=4)
# Effect of DAs on Knowledge

<table>
<thead>
<tr>
<th>Study</th>
<th>Mean Difference</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mathieu, 2010</td>
<td>1.08</td>
<td>[0.65, 1.51]</td>
</tr>
<tr>
<td>Gummersbach, 2015</td>
<td>0.26</td>
<td>[-0.18, 0.70]</td>
</tr>
<tr>
<td>Hersch, 2015</td>
<td>0.75</td>
<td>[0.50, 1.00]</td>
</tr>
<tr>
<td>RE Model</td>
<td>0.70</td>
<td>[0.27, 1.13]</td>
</tr>
</tbody>
</table>
Effect of DAs on Informed Choice

<table>
<thead>
<tr>
<th>Study</th>
<th>Risk Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mathieu, 2010</td>
<td>0.22 [0.10, 0.33]</td>
</tr>
<tr>
<td>Hersch, 2015</td>
<td>0.09 [0.03, 0.14]</td>
</tr>
<tr>
<td>RE Model</td>
<td>0.14 [0.02, 0.27]</td>
</tr>
<tr>
<td>DECISION CONFLICT</td>
<td>Mean difference, Intervention – Control [95% CI]</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Eden, 2015</td>
<td>$-3.80 , [-4.51, -3.09]$</td>
</tr>
<tr>
<td>Hersch, 2015</td>
<td>$0.03 , [-0.21, 0.28]$</td>
</tr>
<tr>
<td>RE Model</td>
<td>$1.87 , [-5.63, 1.89]$</td>
</tr>
</tbody>
</table>
Effect of DAs on Screening Decision

DECIDED TO BE SCREENED  Risk difference, Intervention – Control [95% CI]

Mathieu, 2010  0.03 [ −0.08 , 0.14 ]
Eden, 2015  0.07 [ −0.07 , 0.20 ]
Gummersbach, 2015  −0.07 [ −0.15 , 0.00 ]
Hersch, 2015  −0.13 [ −0.18 , −0.08 ]

RE Model  −0.04 [ −0.13 , 0.05 ]
Conclusions of the systematic review

- **Variability on:**
  - Type and amount of information in the DA
  - Information given to the control group

- **Heterogeneity** in all the observed results

- **Decision Aids:**
  - Increase informed choice
  - Increase knowledge
  - Affect significantly decision conflict and intention to be screened in some studies.
Informing women about benefits and harms
Qualitative study. Designing a DA

- **Design**: Focus groups with guided discussions
  - Decision making about breast cancer screening
  - Acceptability and feasibility of a decision aid (leaflet)

- **Study population**
  - Women aged 40-69 (7 groups, 39 women)
  - Healthcare professionals (2 groups, 23 professionals)

- **Setting and Time**
  - Catalonia and the Canary Islands, in 2015
Conclusions of the qualitative study

- Women positively value receiving information regarding the benefits and risks of breast cancer screening.

- The information on overdiagnosis generates confusion among women and controversy among professionals.

- Faced with the new information presented by the DA, the majority of women express a need of shared decision making.

- Feasibility might be limited by lack of knowledge and attitudes of resistance from healthcare professionals.
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Some comments from women and health professionals

• “That is so crazy!”  Women 68, on overdiagnosis

• “How can I make a decision if it is beneficial to my health? I mean, I don’t quite understand why you’re asking me if I need a tool, when I know it’s beneficial.”  Woman, 51

• “There is enough evidence about benefits of the program and, therefore, they can’t be debated as there are some standards that have already been established by scientific evidence and are not debatable.”  Health professional in a screening program
BENEFICIOS Y EFECTOS ADVERSOS A LARGO PLAZO DE LA DETECCIÓN PRECOZ DEL CÁNCER DE MAMA

Si un grupo de 200 mujeres entre 50 y 69 años se hacen mamografías de cribado cada 2 años, cuando cumplan 80 años...

**BENEFICIOS DEL CRIBADO**

1. Sobrevivirá al cáncer de mama
   - Habría fallecido sin el cribado
   - Los tratamientos de algunas mujeres pueden ser menos agresivos

**CON O SIN CRIBADO**

4. Habrán muerto de cáncer de mama a pesar de haber participado en el cribado

8. Habrán sido diagnosticadas y sobrevivirán
   - Habrían sobrevivido aunque no se hubieran cribado

**EFECTOS ADVERSOS DEL CRIBADO**

2. Serán diagnosticadas y tratadas de un cáncer de mama
   - Este cáncer nunca habría sido una amenaza para su vida

40. Habrán necesitado pruebas adiconales
   - Posteriormente se descartará que hubieran tenido cáncer de mama (falsos positivos)

Por cada muerte evitada por el programa de cribado, 2 mujeres son diagnosticadas y tratadas de un cáncer que nunca hubiera puesto en riesgo su vida.

AUXUANDOTE A DECIDIR
Piloting the acceptability of the DA
Is the DA balanced w.r.t. screening?

- women (n=60):
  - clearly slanted towards: 19%
  - little slanted towards: 27%
  - balanced: 44%
  - little slanted away: 8%
  - clearly slanted away: 2%

- health professionals, men (n=17):
  - clearly slanted towards: 29%
  - little slanted towards: 6%
  - balanced: 29%
  - little slanted away: 6%
  - clearly slanted away: 23%

- health professionals, women (n=26):
  - clearly slanted towards: 29%
  - little slanted towards: 12%
  - balanced: 42%
  - little slanted away: 19%
  - clearly slanted away: 4%
Is the DA helpful?

<table>
<thead>
<tr>
<th>Group</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women (n=60)</td>
<td>24%</td>
<td>42%</td>
<td>29%</td>
<td>5%</td>
</tr>
<tr>
<td>Health Professionals, Men (n=17)</td>
<td>18%</td>
<td>35%</td>
<td>24%</td>
<td>24%</td>
</tr>
<tr>
<td>Health Professionals, Women (n=26)</td>
<td>4%</td>
<td>8%</td>
<td>65%</td>
<td>23%</td>
</tr>
</tbody>
</table>

Decision aid helpful in making decision

Percentage
Would you recommend it?

Would recommend decision aid to women

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Women (n=60)</th>
<th>Health Professionals, Men (n=17)</th>
<th>Health Professionals, Women (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitively yes</td>
<td>53%</td>
<td>29%</td>
<td>27%</td>
</tr>
<tr>
<td>Probably yes</td>
<td>36%</td>
<td>35%</td>
<td>42%</td>
</tr>
<tr>
<td>Not sure</td>
<td>8%</td>
<td>18%</td>
<td>12%</td>
</tr>
<tr>
<td>Probably not</td>
<td>3%</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Definitely not</td>
<td></td>
<td></td>
<td>19%</td>
</tr>
</tbody>
</table>
Ongoing RCT

- **Aim**: Assess the impact of a decision aid on knowledge, informed choice, decisional conflict, and participation in screening.
- **Study protocol**: Based on Hersch, BMJ open 2014.
- **Study sample**: 200 Intervention (new leaflet), 200 Control (standard care)
- **Study population**: Women aged ≃ 50, before being invited to the first screening exam.
- **Instruments**: 2 questionnaires, web or phone.
- **Completion status**: 25%
Conclusions

• It is time for a new risk-based screening approach
  • More research on risk measurement
  • New classification of lesions

• Women want to know and are ready to be informed

• Health professionals would prefer “not to touch it”

• Decision aids can be the tool to engage health professionals and women in share decision making
The InforMa Study Group

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- **Canary Islands Health Service**: L. Perestelo, A. Toledo.
- **ÀreaQ, Evaluation and Qualitative Research**: A. Cardona, N. Codern.
- **Autonomous University of Barcelona**: M. Feijoo.
- **Field work team**: S. Buil, M. Ortega, S. Pla, C. Vinyals, S. Vinyals.
Thank you!
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