Predicting decline in functionality and chemotherapy toxicity: a prospective multicentre study.

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1. Purpose of the study

• Prospective multicentre study:
  – to evaluate the functionality of older cancer patients 2 to 3 months after treatment decision
  – to identify predictive baseline markers for functional decline and severe chemotherapy toxicity

2. Methods (1)

• Inclusion criteria:
  – malignant tumour
    • breast, colorectal, ovarian, lung, prostate, haematological malignancies
  – >70 years
  – treatment decision had to be made
    • at diagnosis
    • at disease progression

2. Methods (2)

• Baseline:
  – Geriatric screening: G8 / Flemish TRST / pain
  – Comprehensive Geriatric Assessment (CGA):
    • Social data
    • Functionality (ADL / IADL / presence of falls)
    • Mobility-Tiredness Test (MOB-T)
    • Mini Mental State Examination (MMSE)
    • Geriatric Depression Scale (GDS-15)
    • Mini Nutritional Assessment (MNA)
    • ECOG-PS / polypharmacy
    • Charlson Comorbidity Index (CCI)

2. Methods (3)

• Follow-up (2 to 3 months after treatment decision):
  – By repeating ADL, IADL and presence of falls
    • Worsening of ADL and IADL: calculated on total scores
    • Worsening of ADL: increase of ≥2 points
    • Worsening of IADL: decrease of ≥1 points

• Patients receiving chemotherapy
  – Treatment related toxicities grade III-IV recorded using the NCI CTCAE, version 4.0 for adverse events.
2. Methods  
- Logistic regressions for identifying explanatory variables (SAS v.9.2)
  - Selection method: stepwise
  - Error levels for entering the model and staying in the model unless otherwise specified: 0.05

3. Results  

<table>
<thead>
<tr>
<th>Diagnosis (%)</th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Breast</td>
<td>40.4</td>
<td></td>
</tr>
<tr>
<td>Colorectal</td>
<td>20.6</td>
<td></td>
</tr>
<tr>
<td>Hematologic</td>
<td>15.9</td>
<td></td>
</tr>
<tr>
<td>Prostate</td>
<td>9.0</td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>7.8</td>
<td></td>
</tr>
<tr>
<td>Ovaries</td>
<td>6.3</td>
<td></td>
</tr>
</tbody>
</table>

- Median age: 76y
- Gender (%): Female 63.5, Male 36.5

3. Results (2)  

- Follow-up data available from 811 patients:
  - Worsening of ADL: observed in 17.2%
  - Worsening of IADL: observed in 38.9%
  - During follow-up, 17.5% of the patients had at least 1 fall.

3. Results (3)  

- Worsening in ADL predicted with logistic regression by:
  - baseline IADL
  - baseline MNA
  - Flemish TRST
  * all p<0.05

3. Results (4)  

- Worsening of IADL predicted in logistic regression by:
  - baseline ECOG-PS
  - Flemish TRST
  - baseline GDS-15
  - chemotherapy
  * all p<0.05

3. Results (5)  

- Presence of falls during follow-up predicted with logistic regression by:
  - presence of falls during the year before inclusion
  - baseline ADL
  - G8
  - baseline living situation
  - baseline disease setting (new diagnosis or progression)
  * all p<0.05
3. Results (6)

- Chemotherapy group only (n=411):
  - Haematologic and non-haematologic grade III-IV toxicities developed both in 16% of the patients.

  - Predictive by logistic regression for:
    - severe haematological toxicity:
      - Type of malignancy (p<0.05)
      - G8 (p<0.1)
    - severe non-haematological toxicity:
      - MNA and ADL (p<0.1)

4. Conclusion

- Parameters from CGA before treatment in older cancer patients can identify at-risk patients for decline in functionality and development of falls.

- Severe chemotherapy toxicity not well predicted by baseline CGA parameters: this effect might be obscured by:
  - the utilization of many different chemotherapy regimens with different toxicity profiles.
  - the presence of both solid tumors and haematological malignancies.

THANK YOU!

To all the patients, both centres and their staff and all of you for your great interest in ‘geriatric oncology’