Patient Reported Outcomes Measures (PROMs) in geriatric patients undergoing major surgery for solid cancer. 90-day preliminary report on 643 patients from the Geriatric Oncology Surgical Assessment and Functional Recovery after Surgery (GOSAFE) study

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DISCLOSURE

**IM**: Olympus EU, Faculty at taTME international courses

The **GOSAFE study** did **not** receive any form of funding by any private company or State agency
Why are we performing poorly?

Disparities in treatments

EUROCARE-5 (2015) unfavorable cancer-related survival among senior adults

De Angelis et al. Lancet Oncol 2014
National Cancer Intelligence Network www.ncin.org.uk
Why are we performing poorly?

(1) Difference between Chronological vs Biological age

**Biological age**

Pete Frates, 34, ALS pt
He inspired the ice bucket challenge
‘Boston College baseball star’

**Chronological age**

Random Italian elderly gentleman, around 80, hospital cafeteria
‘The leopard can not change its spots’

Frailty assessment
(2) Gap between research trials and the real world

Why are we performing poorly?

Clinical Trial Population

0-18 years

18 - 64 years

≥64 years

Actual users

SIOG plenary session, Milan 2016
DFS/PFS have a little value for elderly pts
OS, Functional recovery, regaining independence are outcomes that matter to pts

89,574 pts with cancer from the Medicare database
Disability and lack of independence seem to impact cancer patients more than the cancer prognosis per se
What is necessary to make it better?
To put outcomes relevant to patients at the center of a large collaborative study

- Collaboration of a multidisciplinary group from the ESSO and the SIOG Surgical Task Force
- clinicaltrials.gov (Identifier: NCT03299270)
- REAL WORLD INVESTIGATION Observational Study – 26 centers
Inclusion Criteria

✓ All patients aged ≥70 years
✓ elective major surgery with curative or palliative intent for solid malignancy
✓ (cognitive impairment was not considered an exclusion criterion)

Exclusion criteria

✓ Patients undergoing emergent/urgent surgery
✓ planned hospital stay less than 48 hours

Centers were asked to provide the minimum 20 consecutive patients, if not possible centers were excluded from the analysis of the primary and secondary outcome.
Outcome measures

Primary outcome

✔ QoL- EQ5D-3L
(3-point scale: mobility, self-care, usual activities, pain/discomfort, anxiety/depression)

- Comparing the EQ 5D-3L index at 3-6m
- Comparing the EQ 5D-3L VAS at 3-6m
Outcome measures

Secondary outcomes

✓ **Functional recovery (FR)** 📋 restoration of ADL, mobility, and cognitive status at 3-6m
  
  • Composite measure of **ADL (≥5), TUG (<20 sec) and MiniCog (>2)**
  
  • Complete FR (cFR) ☑ preservation/improvement of baseline results of all the three reported tests
  
  • Partial FR (pFR) ☑ preservation/improvement of 2/3 of the functional assessment tests
  
  • Functional deterioration (FD) ☑ decline of 3 domains

✓ 3- and 6- month postoperative morbidity and mortality
✓ Correlation between risk factors (data from the frailty assessment) and postop outcomes, QoL and FR
Cancer patients (≥ 70yo) undergoing surgery for solid malignancy with curative or palliative intent

Exclusion Criteria
- Hospital stay ≤ 48 hours
- Emergent/urgent surgery

Baseline Evaluation

Surgery and 30-day morbidity & mortality

3-month postop functional outcomes

6-month postop functional outcomes

Preop Assessment
- ASA score
- CCI
- FIRST
- GB
- Living situation
- History of falls/delirium
- Polytherapy
- Neoadjuvant treatment
- Geriatrician involvement
- Laboratory blood tests*

Postop Assessment
- Mortality & Morbidity
- Living situation
- Nutritional supplement
- Rehabilitation program
- Geriatrician involvement
- Adjuvant treatment

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QoL + Function
- EQ-SD-3L
- ADL
- Mini-Cog
- NRS
- TUG
- ECOG-PS

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QoL + Function
- EQ-SD-3L
- ADL
- Mini-Cog
- NRS
- TUG
- ECOG-PS

*Laboratory blood tests include: hemoglobin, albumin and creatinine
Demographic data (February 2017-September 2018)

643 pts underwent major cancer surgery curative (94%) vs. palliative (6%) intent.

388 pts Minimally Invasive Surgery (60.3%)

506 with 90-day postop comprehensive assessment.
<table>
<thead>
<tr>
<th>Test</th>
<th>N(%) 643</th>
<th>Test</th>
<th>N(%) 643</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>G-8 Total score</strong></td>
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<tr>
<td>G-8 ≤14</td>
<td>434 (67.6)</td>
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<tr>
<td>G-8 &gt;14</td>
<td>208 (32.4)</td>
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<tr>
<td><strong>ADL SCORE</strong></td>
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<tr>
<td>&lt;5</td>
<td>52 (8.2)</td>
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<tr>
<td>≥5</td>
<td>589 (91.8)</td>
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<td><strong>ASA score</strong></td>
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<tr>
<td>1-2</td>
<td>305 (48.0)</td>
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<td>3-4</td>
<td>330 (52.0)</td>
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<td><strong>PS ECOG</strong></td>
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<tr>
<td>ECOG 0</td>
<td>349 (54.5)</td>
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<tr>
<td>ECOG 1</td>
<td>190 (29.7)</td>
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<tr>
<td>ECOG≥2</td>
<td>101 (15.8)</td>
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<td><strong>CACI</strong></td>
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<tr>
<td>3-6</td>
<td>401 (64.1)</td>
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<tr>
<td>≥7</td>
<td>225 (35.9)</td>
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<td><strong>fTRST – Variables</strong></td>
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<tr>
<td>0</td>
<td>159 (24.8)</td>
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<tr>
<td>≥2</td>
<td>237 (38.5)</td>
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<tr>
<td>Missing</td>
<td>246 (36.7)</td>
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<tr>
<td><strong>MINICOG Total score</strong></td>
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<tr>
<td>0-2 pos screen dementia</td>
<td>134 (21.1)</td>
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<tr>
<td>3-5 neg screen dementia</td>
<td>500 (78.9)</td>
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<td><strong>Time up and Go</strong></td>
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<tr>
<td>≤ 20 sec</td>
<td>546 (93.8)</td>
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<tr>
<td>&gt;20 sec</td>
<td>36 (6.2)</td>
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<tr>
<td><strong>Nutritional status score</strong></td>
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<tr>
<td>Normal</td>
<td>407 (63.9)</td>
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<tr>
<td>Mildly impaired</td>
<td>163 (25.6)</td>
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<tr>
<td>Moderately impaired</td>
<td>53 (8.3)</td>
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<tr>
<td>Severely impaired</td>
<td>14 (2.2)</td>
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# 30-90 day Postoperative outcomes

## 506 pts

<table>
<thead>
<tr>
<th>30-day Mortality</th>
<th>90-day Mortality</th>
<th>25 pts (5%)</th>
<th>35 pts (7%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fit</strong> (ADL&gt;5, TUG&lt;20sec, Minicog&gt;2)</td>
<td></td>
<td>18/329 (4.2%)</td>
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<tr>
<td><strong>Two impaired</strong> (ADL&gt;5, TUG&lt;20sec, Minicog&gt;2)</td>
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<td>2/23 (8.7%)</td>
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<tr>
<td><strong>All impaired</strong> (ADL&gt;5, TUG&lt;20sec, Minicog&gt;2)</td>
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<td>2/9 (22.2%)</td>
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</tbody>
</table>

## 471 pts

<table>
<thead>
<tr>
<th>90-day morbidity</th>
<th>236 (50%), 105&gt;1 (22.3%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD 1-2</td>
<td>183 (38.8%)</td>
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<tr>
<td>CD 3-4</td>
<td>53 (11.2%)</td>
</tr>
<tr>
<td><strong>Fit</strong> (ADL&gt;5, TUG&lt;20sec, Minicog&gt;2)</td>
<td>144/311 (46.3%)</td>
</tr>
<tr>
<td><strong>Two impaired</strong> (ADL&gt;5, TUG&lt;20sec, Minicog&gt;2)</td>
<td>16/21 (76%)</td>
</tr>
<tr>
<td><strong>All impaired</strong> (ADL&gt;5, TUG&lt;20sec, Minicog&gt;2)</td>
<td>5/7 (71%)</td>
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</tbody>
</table>
EQ-5D VAS (471pts)

- 296 (67.0%)
- 69 (15.6%)
- 49 (11.1%)
- 28 (6.3%)
EQ-5D index (471 pts)

Mean Preop 0.76 (SD 0.21)
Mean Postop 0.80 (SD 0.22)

Moderate to severe symptoms

%
90 day Functional Recovery (471pts)

- **Functional Decline (ADL+TUG+MiniCog)**: 42.47%
- **Partial Functional Recovery**: 34.95%
- **Complete Functional Recovery (ADL≥5 + TUG<20sec + MiniCog>2)**: 29.10%
- 105 Pts with >1 complication
Conclusion

• **GOSAFE** study provides a real world picture of unselected older patients with cancer undergoing **major surgery**

• Enrolment and 6m follow-up completed (Oct 31\textsuperscript{th}, 2019) – 1007 patients (471 presented today)

• Single frailty screening provides inconsistent estimate (combination?)

• Mortality and Morbidity data prove that **major surgery in senior adult can be safe**

• 1/3 of patients who undergo surgery have a severe functional decline at 90 days
  2/3 of patients who undergo surgery return to be independent (partial and complete FR at 90 days)

• QoL improves after surgery above all in terms of reduction of pain anxiety and depression

• Final data will allow to improve understanding QoL and FR

• Correlation between risk factors (data from the frailty assessment) and postop outcomes, QoL and FR