Radioterapia Oncologica: l’evoluzione al servizio dei pazienti
The radiotherapy omission within the Sinodar One: Survival and Relapse Outcomes

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Background

Sinodar trial

From 04/2015 to 03/2018

822 enrolled pts

403 standard arm

419 experimental arm
Background

Median FUP: 3 y

5-year LR: 6.9% VS 3.3% (p = 0.444)

5-year OS: 98.9% VS 98.8% (p = 0.936)

These results do not support the use of routine ALND
Aims

✓ Re-analysis of SINODAR-ONE data focusing on the omission of radiotherapy
✓ Dosimetric study of axillary levels
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Results

Data confirmed by RT centers: 427 pts (51.9%)  
355 patients underwent RT

The radiotherapy techniques:
- 220 3D conformal
- 80 VMAT
- 46 IMRT
- 2 Tomo
- 1 IORT
- 6 patients the technique used was not known
Fractionation

- 5 fractions: 2 pts
- Hypofractionation: 218 pts
- Conventional: 134 pts
- IORT: 1 pts

Different schemas
10-20 fractions
Results

Control arm

169 RT
50 LRI
119 only breast

Study arm

186 RT
17 LRI
169 only breast per protocol

9% protocol deviation
Results

Control arm  169 pts

- 0 death
- 2 distant relapse

Study arm  169 pts

- 2 death
- 2 distant relapse
- 1 LR same QUAD
- 1 LR different QUAD

No axillary recurrence

no significant differences
Aims

✓ Re-analysis of SINODAR-ONE data focusing on the omission of radiotherapy
✓ Dosimetric study of axillary levels
Materials & methods

- Dosimetric study was performed in 2 centers
- Retrospective contouring of 5 different levels (I-IV and IMC)
- Calculated EQD2 of for mean dose of all axillary levels ($\alpha/\beta=3$)
- Plans were not optimized for dose to axilla
Results

Dosimetric analysis

Technique
• 3D: 16 pts
• VMAT: 56 pts

Irradiation field
• Local RT: 53 pts
• Locoregional RT: 19 pts

72 pts
### Results

**Mean dose in EQD2**

<table>
<thead>
<tr>
<th></th>
<th>Median I lev</th>
<th>Median II lev</th>
<th>Median III lev</th>
<th>Median IV lev</th>
<th>Median CMI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>local RT</strong></td>
<td>28.20 (DS 10.1)</td>
<td>13.13 (DS 6.7)</td>
<td>8.12 (DS 6.2)</td>
<td>1.99 (DS 4.2)</td>
<td>10.92 (DS 5.4)</td>
</tr>
<tr>
<td><strong>locoregional RT</strong></td>
<td>36.18 (DS 8.1)</td>
<td>29.42 (DS 11.0)</td>
<td>43.2 (DS 9.9)</td>
<td>48.47 (DS 5.2)</td>
<td>18.71 (DS 6.9)</td>
</tr>
</tbody>
</table>

**α/β=3**

The mean dose to I level is near half of prescription dose.
Discussion

• Plans are not different to clinical practice
• Dose on I-II levels represent the normal dose diffusion
• The clinical impact of this dose is not known

but probably this dose has no impact
Discussion

In mastectomy subgroup there is NO differences in:

- 5-y OS
- 5-y DFS

 Same results without RT
Take home message

- SINODAR ONE is principally a surgical study
- Regional radiotherapy could be omitted in selected cases
- The dose to I level could be irrelevant
- AIRO position paper is needed
Grazie

ai centri partecipanti per l’impegno...

...a tutti voi per l’attenzione