



XXXII CONGRESSO NAZIONALE AIRO  
XXXIII CONGRESSO NAZIONALE AIRB  
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# AIRO2022

Radioterapia di precisione per un'oncologia innovativa e sostenibile

BOLOGNA, 25-27 NOVEMBRE  
PALAZZO DEI CONGRESSI



Associazione Italiana  
Radioterapia e Oncologia clinica



Società Italiana di Radiobiologia



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**Il downstaging potrebbe essere considerato un predittore precoce degli outcomes di sopravvivenza nel tumore del retto: risultati di una pooled analysis di studi randomizzati**

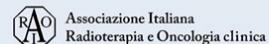
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Gemelli



Fondazione Policlinico Universitario Agostino Gemelli IRCCS  
Università Cattolica del Sacro Cuore





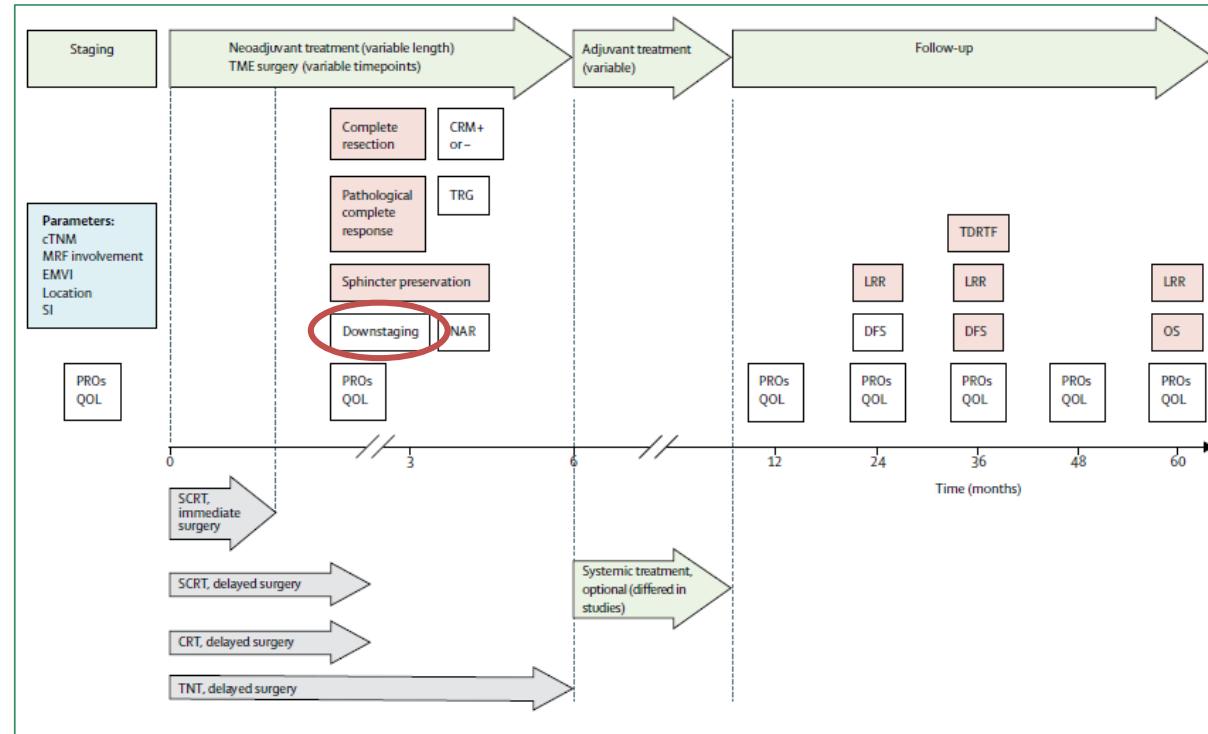
## DICHIARAZIONE

Relatore: Angela Romano

Come da nuova regolamentazione della Commissione Nazionale per la Formazione Continua del Ministero della Salute, è richiesta la trasparenza delle fonti di finanziamento e dei rapporti con soggetti portatori di interessi commerciali in campo sanitario.

- Posizione di dipendente in aziende con interessi commerciali in campo sanitario (**NIENTE DA DICHIARARE**)
- Consulenza ad aziende con interessi commerciali in campo sanitario (**NIENTE DA DICHIARARE**)
- Fondi per la ricerca da aziende con interessi commerciali in campo sanitario (**NIENTE DA DICHIARARE**)
- Partecipazione ad Advisory Board (**NIENTE DA DICHIARARE**)
- Titolarità di brevetti in compartecipazione ad aziende con interessi commerciali in campo sanitario (**NIENTE DA DICHIARARE**)
- Partecipazioni azionarie in aziende con interessi commerciali in campo sanitario (**NIENTE DA DICHIARARE**)

## Background



Fokas et al Lancet Oncol 2020



## Background

Definition: reduction in T-category, N-category or pathological stage of disease compared to preoperative

Impact on survival outcomes is still to be defined

**The aim of this study is the evaluation of downstaging impact on survival outcomes in a pooled dataset of several randomized trials of nCRT in LARC**



## Materials and Methods



- The EORTC trial (Bosslet et al. 2006)
- The French trial (Gerard et al. 2006)
- The German trial (Sauer et al. 2004)
- The German trial (Roedel et al. 2015)
- The TROG trial (Ngan et al. 2012)
- The ACCORD trial (Gerard et al. 2012)
- The INTERACT trial (Valentini et al. 2019)
- The I-CNR-RT trial (Sainato et al. 2014)
- The Polish II trial (Bujko et al. 2016)





## Materials and Methods

### Inclusion criteria

- Age  $\geq 18$  years
- nCRT treatment followed by surgery  $\pm$  CT
- Availability of information on at least one of clinical and pathological T-, N-, or stage downstaging

### Exclusion criteria

- Conservative surgery approach
- SCRT
- cM+



## Materials and Methods

Downstaged patient



Difference of clinical and pathological stages (respectively on T value, N value and the TNM stage)  $\geq 1$

Kaplan Meier curve, Logrank test and univariate logistic regression

p-value < 0.01

- 5yOS
- 2yDMFS
- 2yDFS



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# Results

4167 of 9564 LARC patients satisfied the inclusion criteria

Characteristics	Number of patients (%) 4167
<b>Median age</b> years (range)	62 (55- 68)
<b>Gender</b>	
Female	1297(30.4)
Male	2867(68.8)
NA	3 (0.8)
<b>cT</b>	
1	142 (3.4)
2	400 (9.6)
3	3294 (79)
4	266 (6.4)
NA	65 (1.6)
<b>cN</b>	
0	1210 (29)
1	1630 (39.1)
2	199 (4.8)
NA	1128 (27.1)
<b>Clinical staging</b>	
1	29 (0.7)
2	1130 (27.1)
3	1829 (43.9)
NA	1179 (28.3)
<b>neoAdj Chemo Type</b>	
5FU.OXI	1376 (33)
5FUbased	2791 (67)
<b>Median RT dose</b> Gy (range)	50 (45 - 50.4)

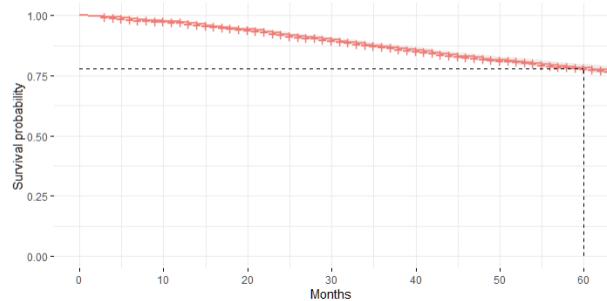
Characteristics	Number of patients (%) 4167
<b>pT</b>	
0	667(16)
1	252 (6)
2	1238 (29.7)
3	1861(44.7)
4	146(3.5)
NA	3 (0.1)
<b>pN</b>	
0	2964 (71.1)
1	905 (21.7)
2	279 (6.7)
NA	19 (0.5)
<b>Patological staging</b>	
pCR	619 (14.9)
1	1196 (28.7)
2	1146 (27.5)
3	1184 (28.4)
na	22 (0.5)
<b>Downstaging T</b>	
0	1982 (47.6)
1	2117 (50.8)
NA	68 (1.6)
<b>Downstaging N</b>	
0	1772(42.5)
1	1263 (30.3)
NA	1132 (27.2)
<b>Downstaging stage</b>	
0	1186 (28.5)
1	1795 (43)
NA	1186 (28.5)
<b>Adj Chemotherapy</b>	
Yes	1393 (33.4)
Not	2774 (66.6)





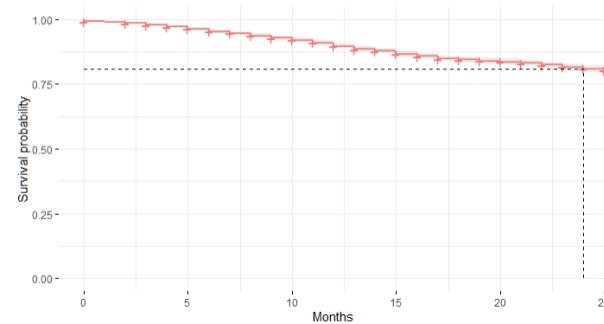
## Results

### Overall Survival



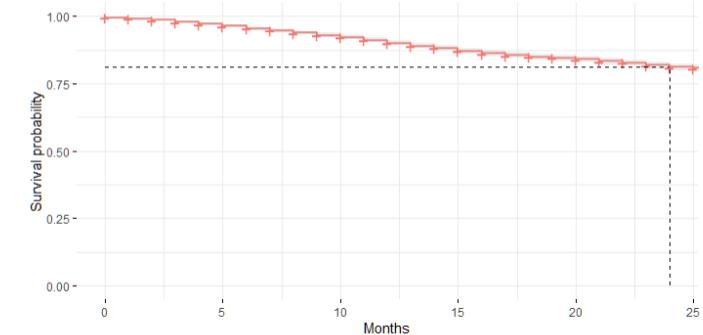
5y OS 78.00%  
(95% CI: 76.80 - 79.70)

### Disease Free Survival



2y DFS 80.80%  
(95% CI: 79.60 - 82.10)

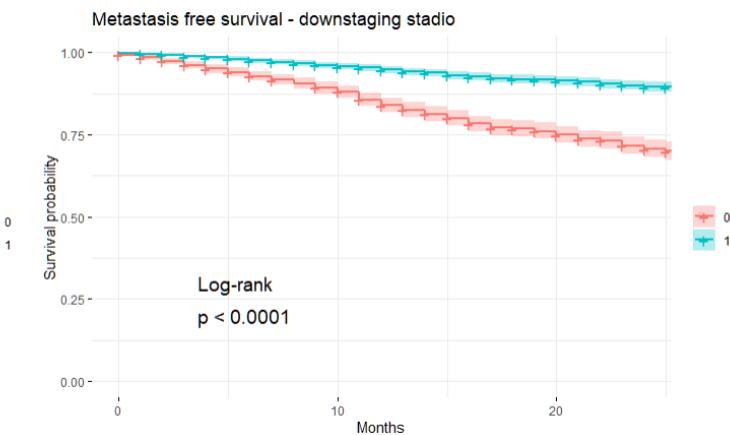
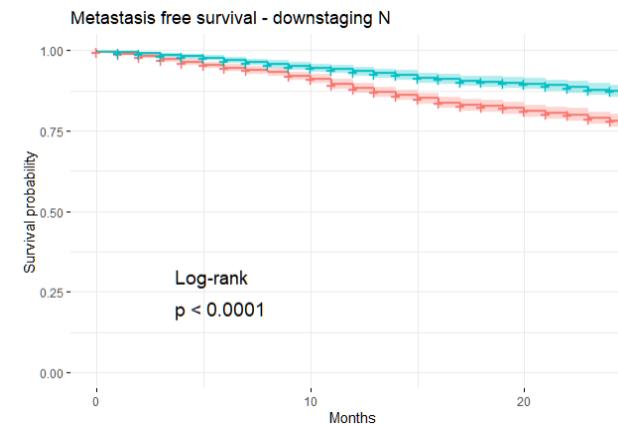
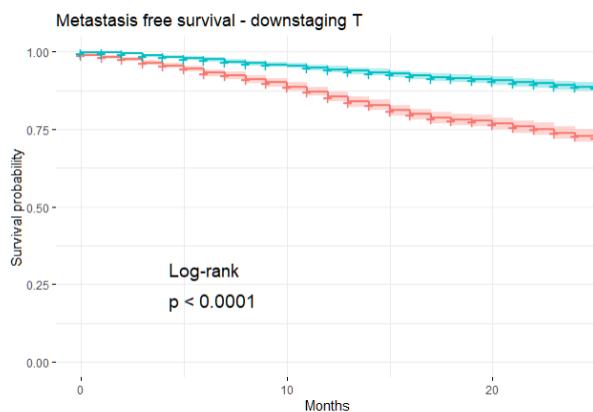
### Metastasis Free Survival



2y DMFS 81.1%  
(95% CI: 79.80 - 82.30)

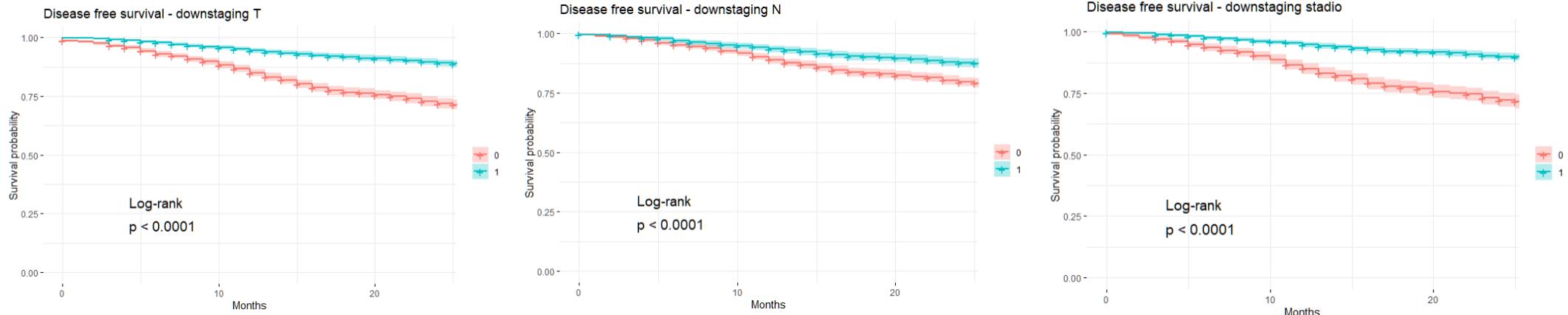
# Results

## 2yDMFS



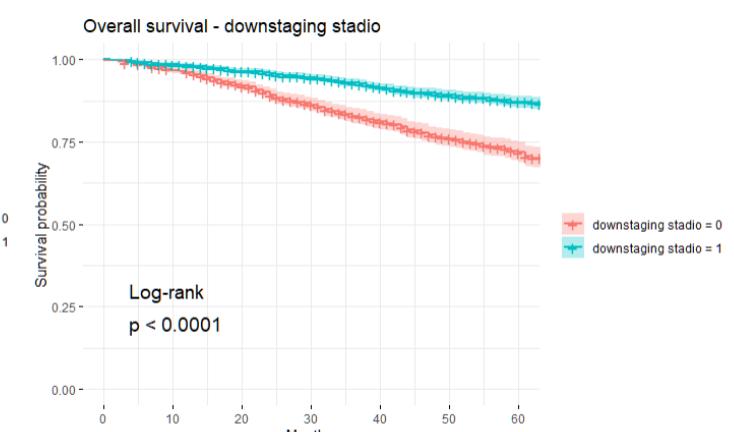
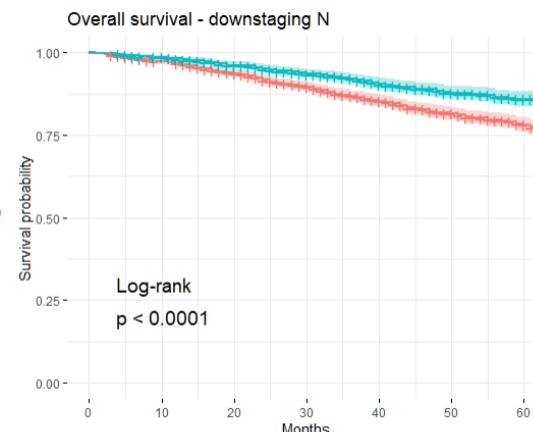
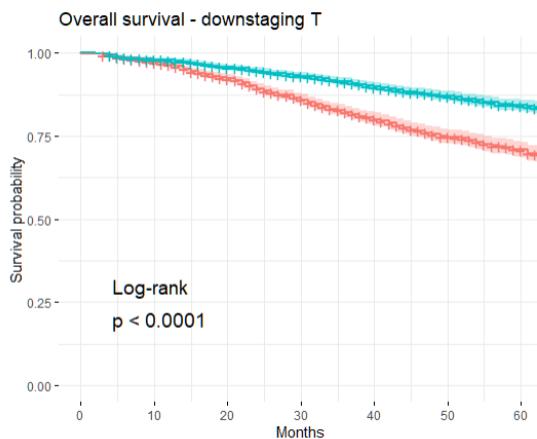
# Results

## 2yDFS



# Results

## 5yOS





## Conclusions

According to the findings obtained in the pooled analysis presented in the current study, downstaging was favorably associated with all survival and disease control outcomes.

Further analysis on this endpoint could lead to the identification of different disease subgroups that could benefit from targeted treatment strategies in the perspective of personalized medicine.