

Multicenter retrospective study comparing dose intensification versus standard regimen in patients affected by locally advanced rectal cancer treated with preoperative radiochemotherapy

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# Study plan

Multicenter retrospective study – 12 participating centers

Actual accrual: 524 pts - Expected accrual: +700 pts

## Paziente with LARC

### Inclusion criteria:

- Preop RCHT with fluoropyrimidine  
Any RT dose (boost vs no boost)
- Possible boost on N+
- Availability of histological report

### Exclusion criteria:

- Induction/consolidation CHT
- No surgery

BOOST

vs

NO BOOST

### Study I:

- Retrospective comparison between standard and boost in the overall population.
- pCR and downstaging analysis by *propensity score matching*
- Sphincter preserving surgery comparison
- Treatment and perioperative toxicity analysis

### Study II:

- Computing predictive model of pCR/downstaging taking into account: RT dose, time to surgery (stratification) and distance from the anal verge
- Local and distant relapse
- Survival

# Data update - results

- Data from the first 524 patients

Boost dose range: 53.8-56 Gy

Patients' characteristics			
Age	63 (29-88)		
		ypT0	89 (29.5%)
		ypTis	1 (0.5%)
		ypT1	20 (6.5%)
cT2	30 (10%)	ypT2	79 (26%)
cT3	232 (77%)	ypT3	105 (35%)
cT4	39 (13%)	ypT4	7 (2.5%)
cN0	103 (34%)	ypN0	220 (73%)
cN1	105 (35%)	ypN1	53 (17.5%)
cN2	93 (31%)	ypN2	18 (6%)
		ypNx	10 (3.5%)
Low	222 (42%)		
Medium	186 (35,5%)		
High	116 (22,5%)		

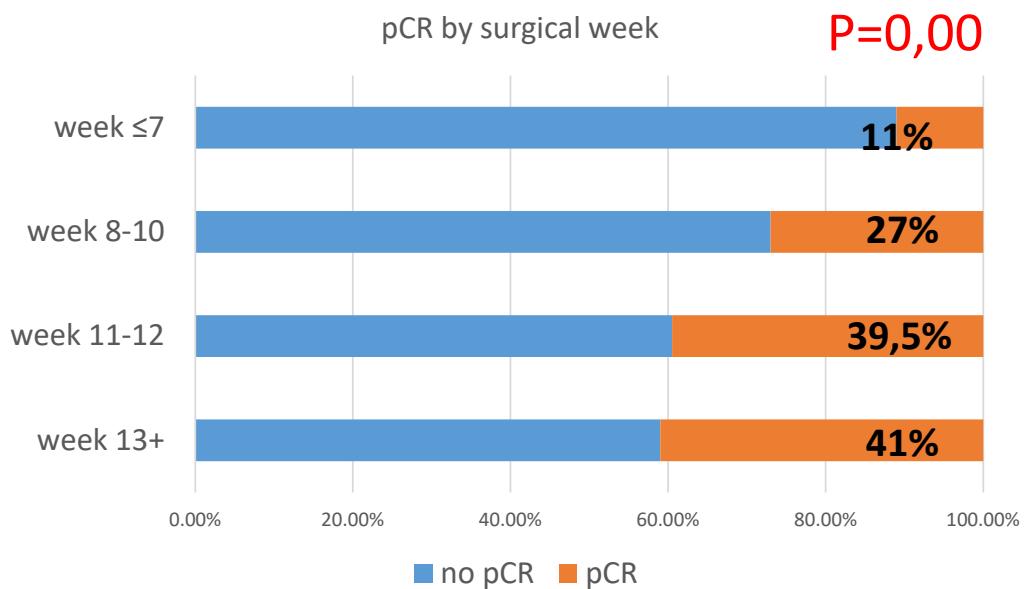
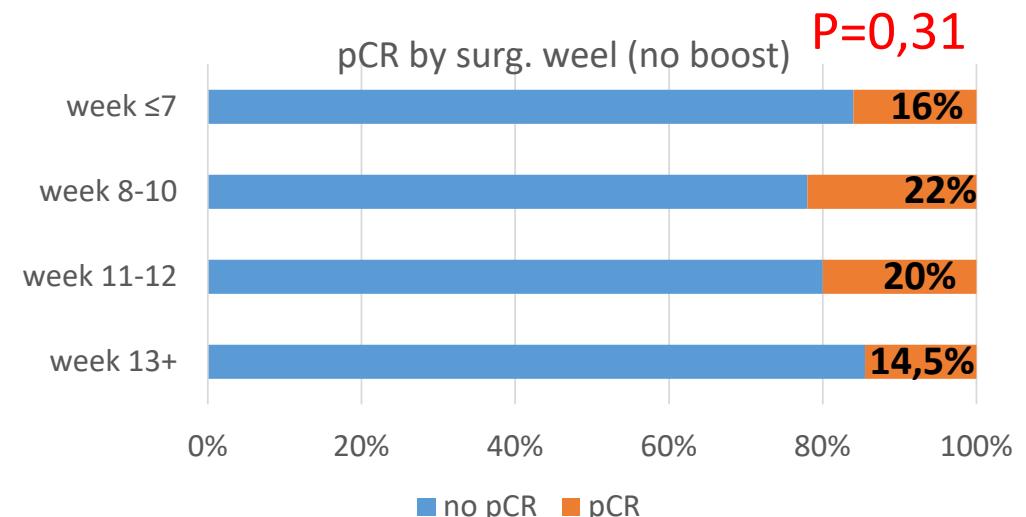
	GU	GY	Gynecological	Skin	Hematological
G0	222	104	294	256	265
G1	62	111	6	35	19
G2	16	65	1	6	15
G3	2	17	0	4	2
G4	0	4	0	0	0

Surgical toxicity	
Dehiscence	22
Sepsis	5
Pneumonia	2
Pancreatitis	1
Mild iron deficiency	1
Subocclusion	3
Sacral fluid collection	4

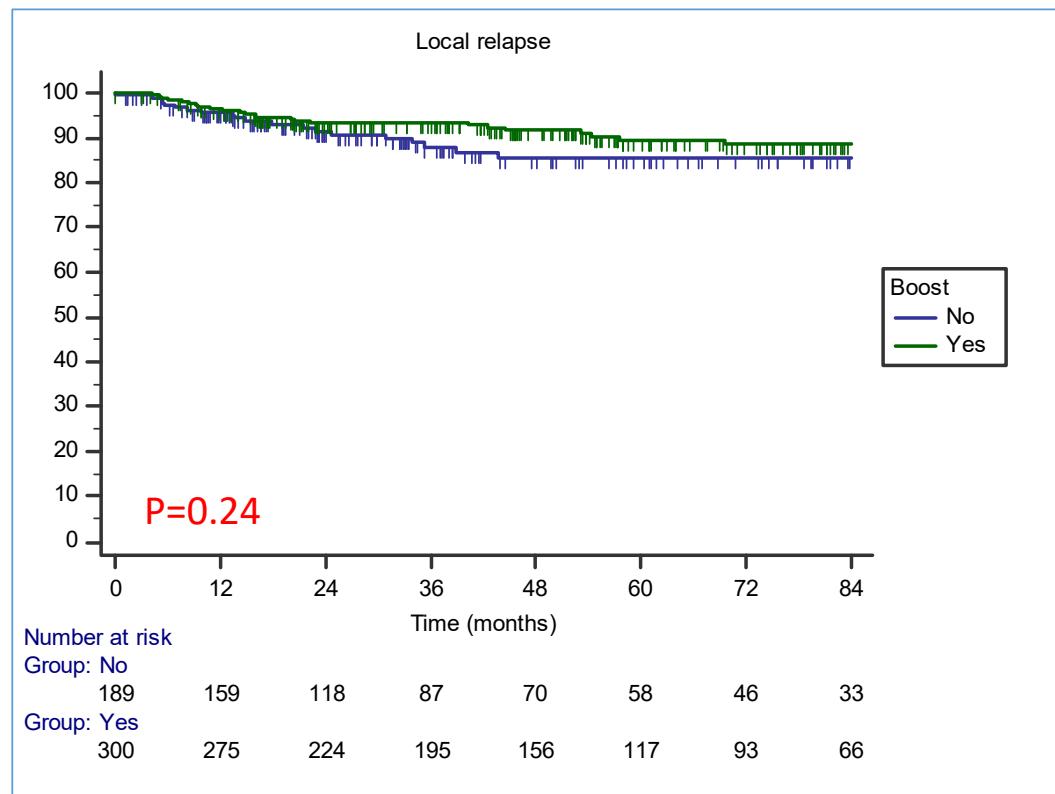
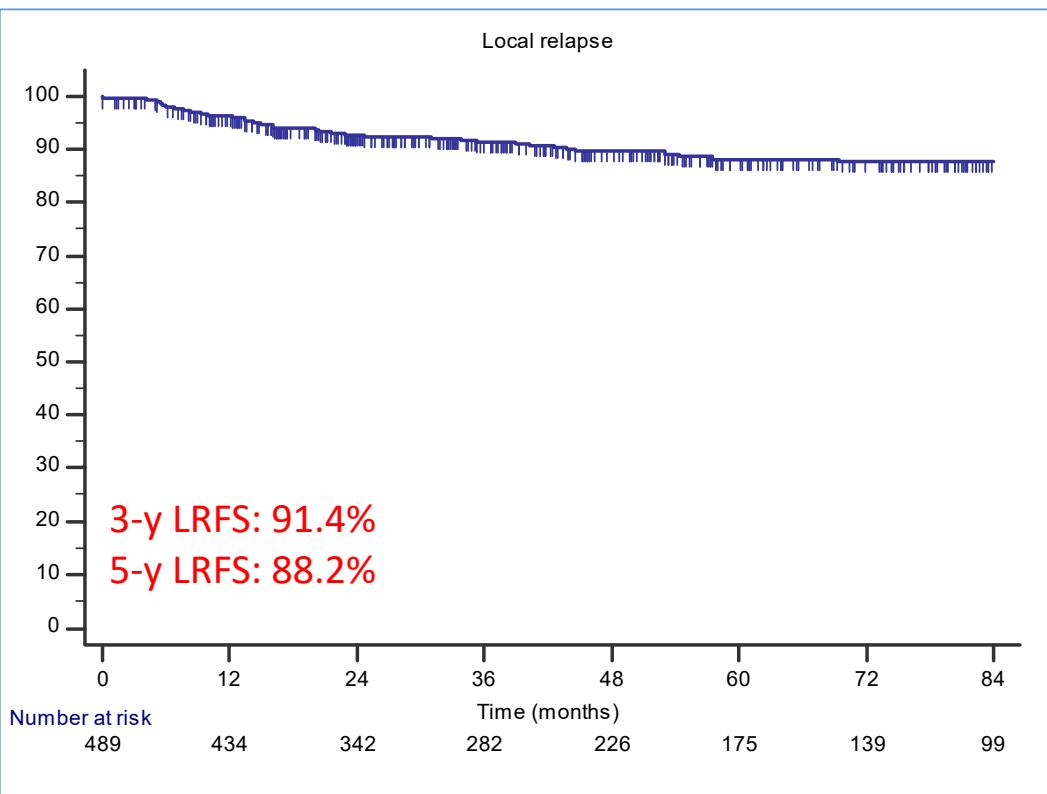
# Data update - results

## Acute toxicity analysis

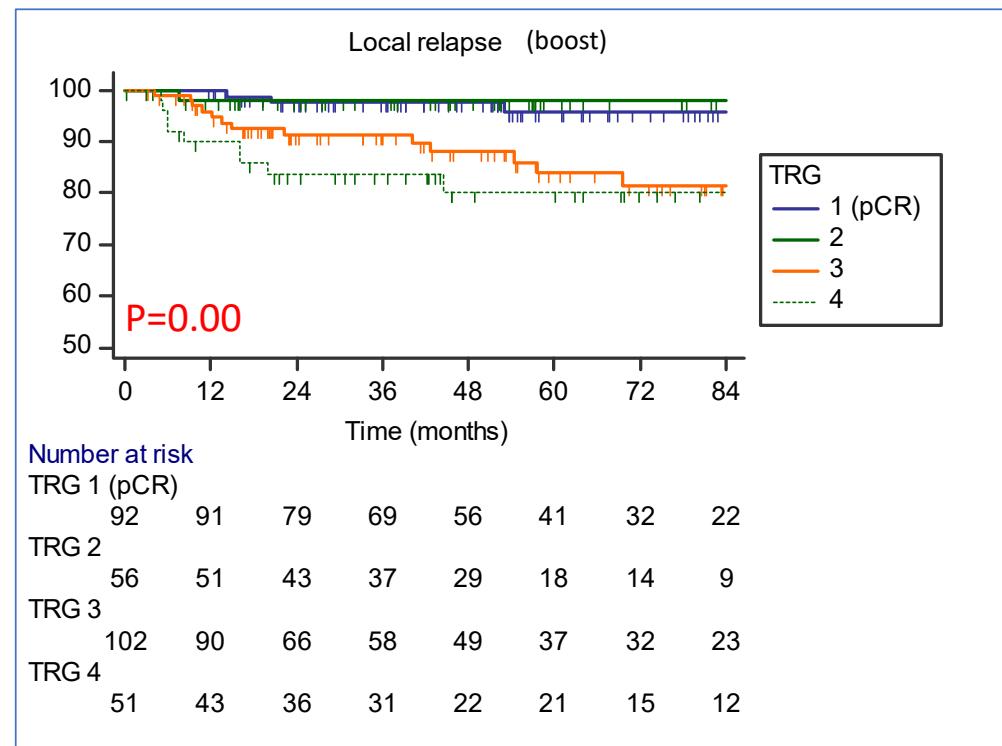
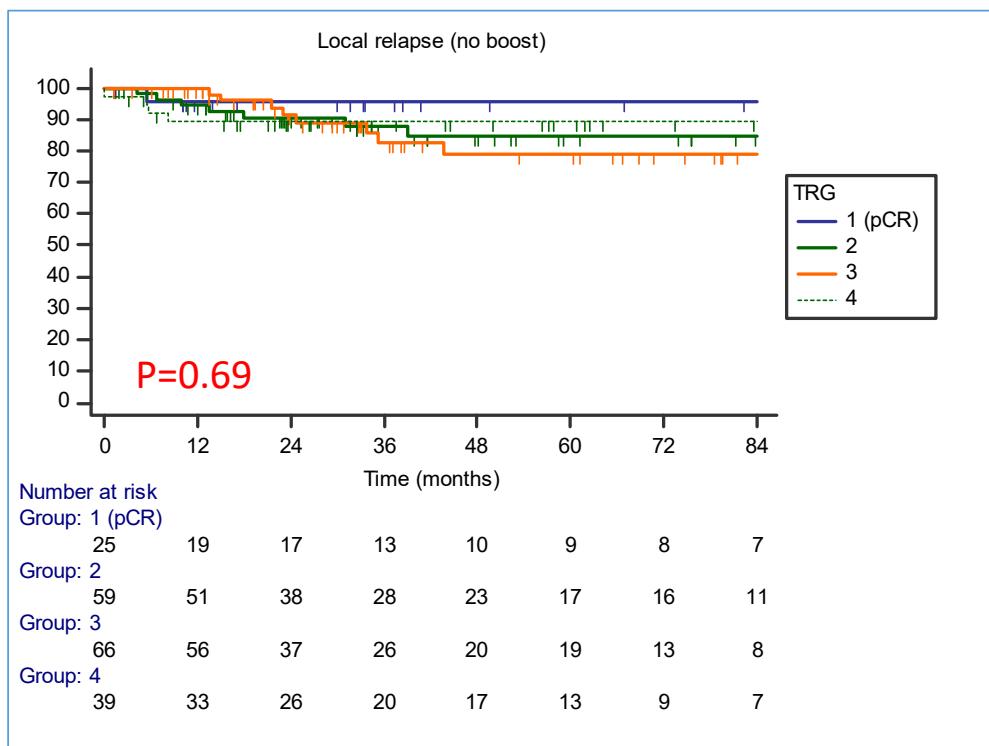
	G0	G3+	p
<b>GU No boost</b>	99.6%	0.4%	0.83
<b>GU Boost</b>	99.7%	0.3%	
<b>GI No boost</b>	97.8%	2.2%	0.01
<b>GI Boost</b>	93.1%	6.9%	
<b>Skin No boost</b>	100%	0%	0.03
<b>Skin Boost</b>	98.7%	1.3%	



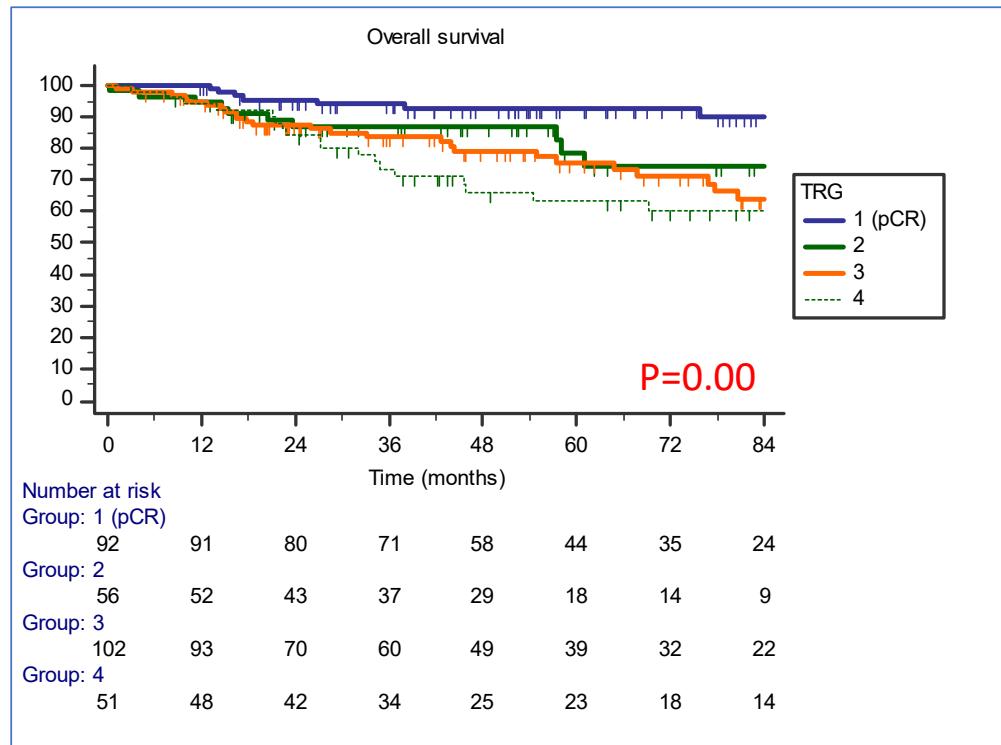
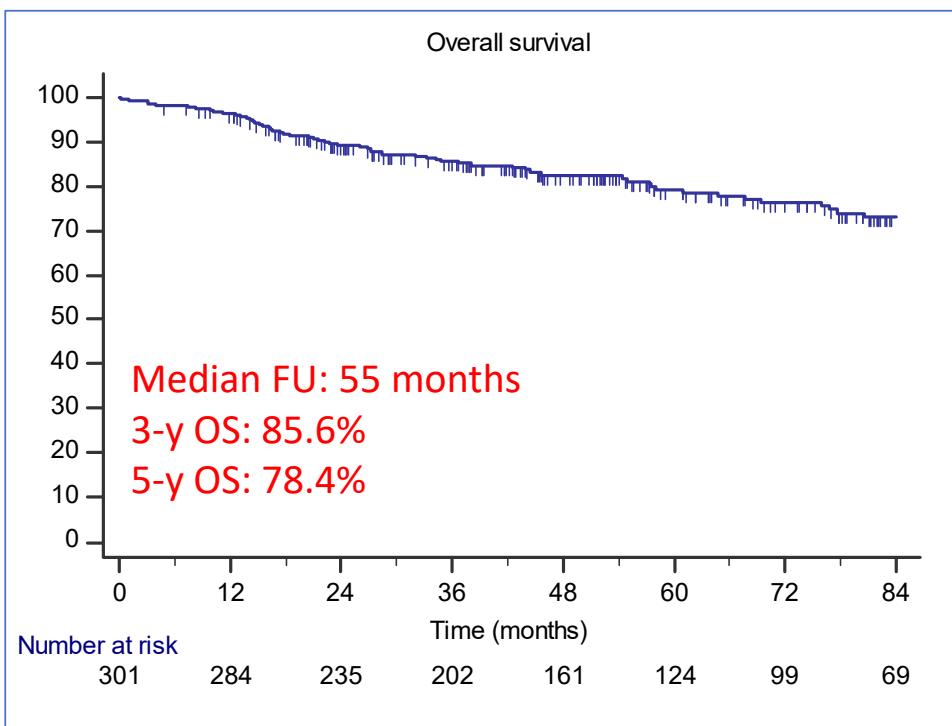
# Data update – results



# Data update – results



# Data update – results (boost only)



Abstract submission to AIRO

Thanks to all Centers!

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