

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

Luca Nicosia, MD

IRCCS Sacro Cuore Don Calabria Hospital

Study plan

Multicenter retrospective study – 13 participating centers

Final accrual: **1026 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

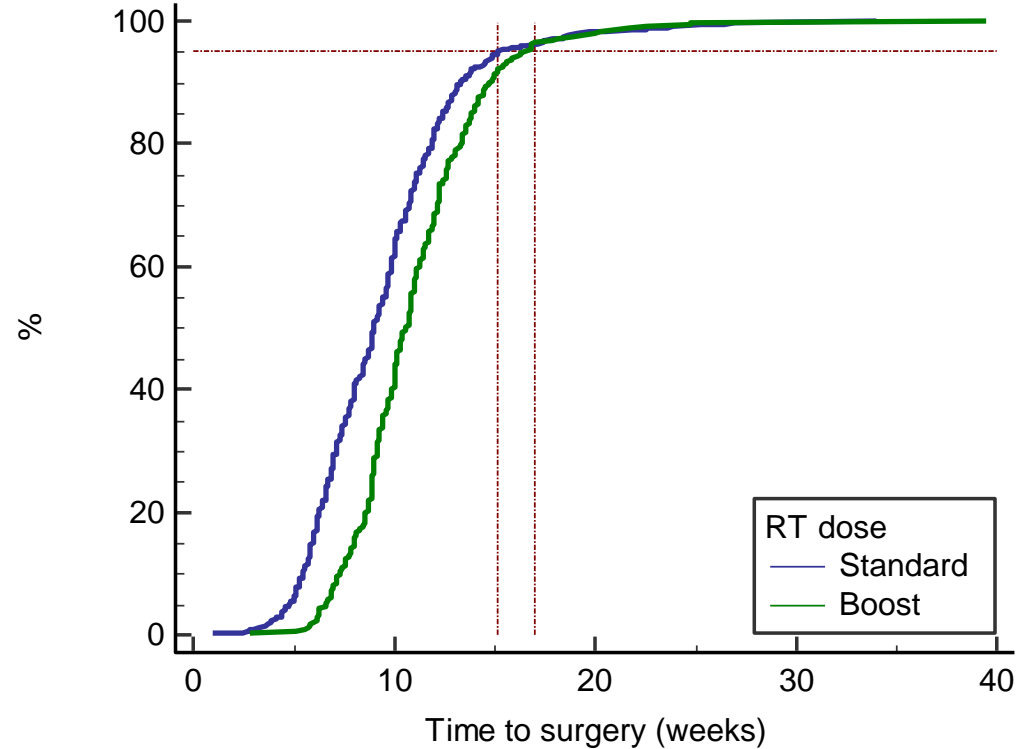
Results

Boost dose range: 53.8-60 Gy

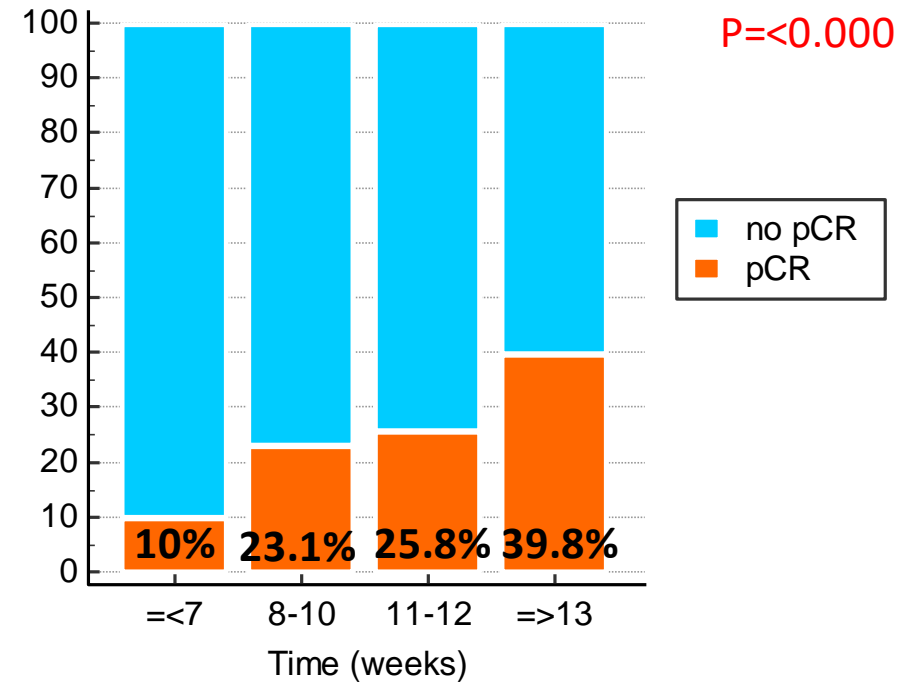
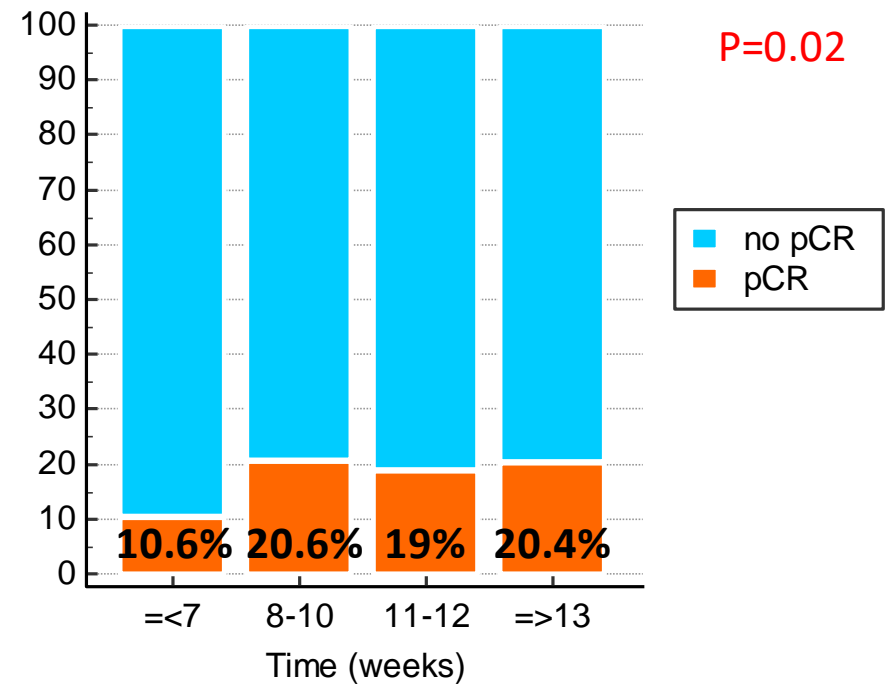
Patients' characteristics			
Age	63 (22-88)		
		ypT0	177 (22.5%)
		ypTis	1 (0.1%)
		ypT1	55 (6.9%)
cT2	86 (11%)	ypT2	199 (25%)
cT3	615 (77%)	ypT3	336 (42%)
cT4	99 (12%)	ypT4	30 (3.5%)
cN0	224 (28%)	ypN0	560 (70%)
cN1	332 (41.5%)	ypN1	171 (21.5%)
cN2	244 (30.5%)	ypN2	57 (7%)
		ypNx	10 (1.5%)
Low	348 (43.5%)		
Medium	348 (43.5%)		
High	104 (13%)		

Acute toxicity analysis			
	G2	G3+	p
GU No boost	17.2%	1.4%	0.01
GU Boost	20.4%	5.1%	
GI No boost	22.4%	1.5%	0.000
GI Boost	20.4%	6.3%	
	No toxicity	Yes toxicity	
Surg No boost	67%	33%	0.000
Surg Boost	86%	14%	

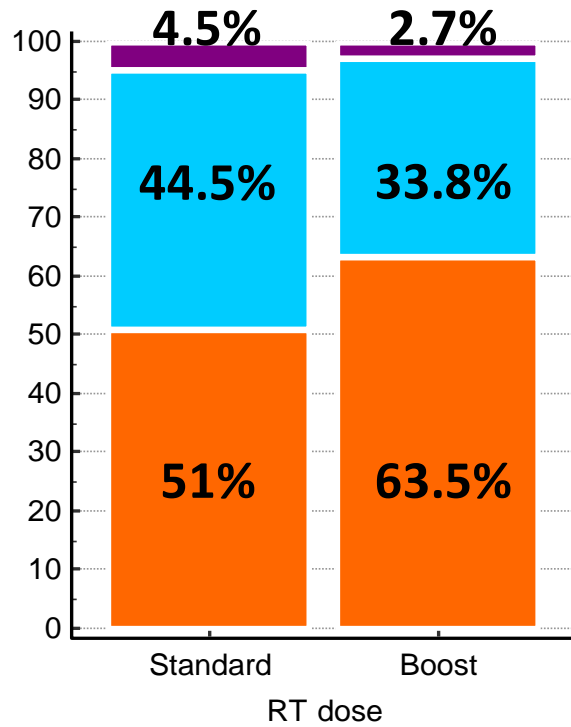
Results



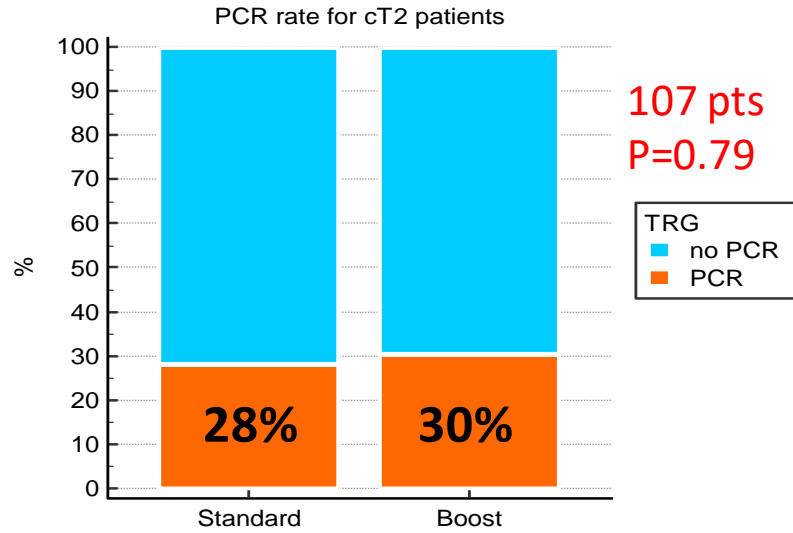
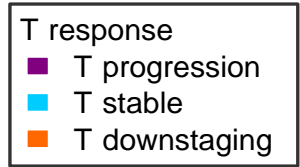
95% of pCR
 No boost: within the 15 week
 Boost: within the 17 week



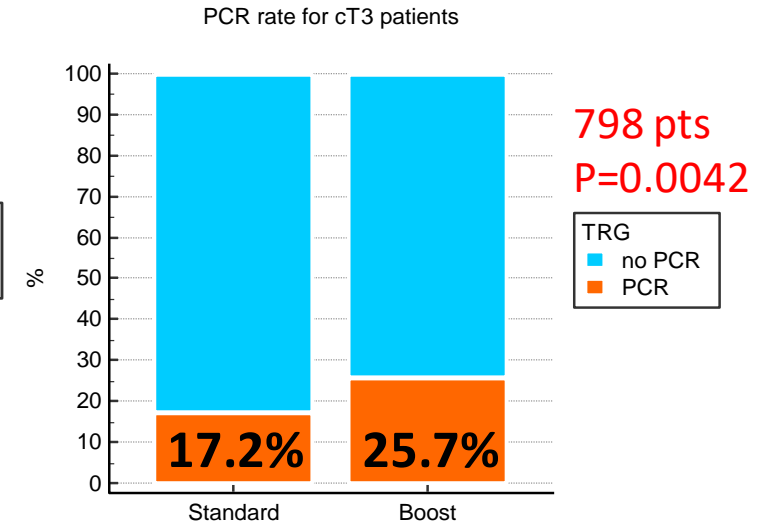
Results



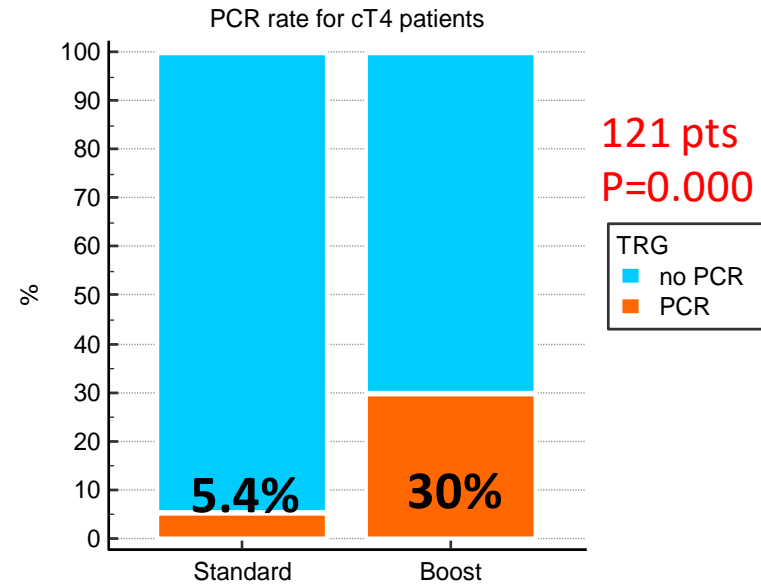
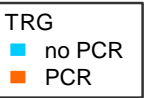
P=0.000



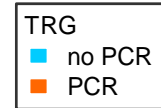
107 pts
P=0.79



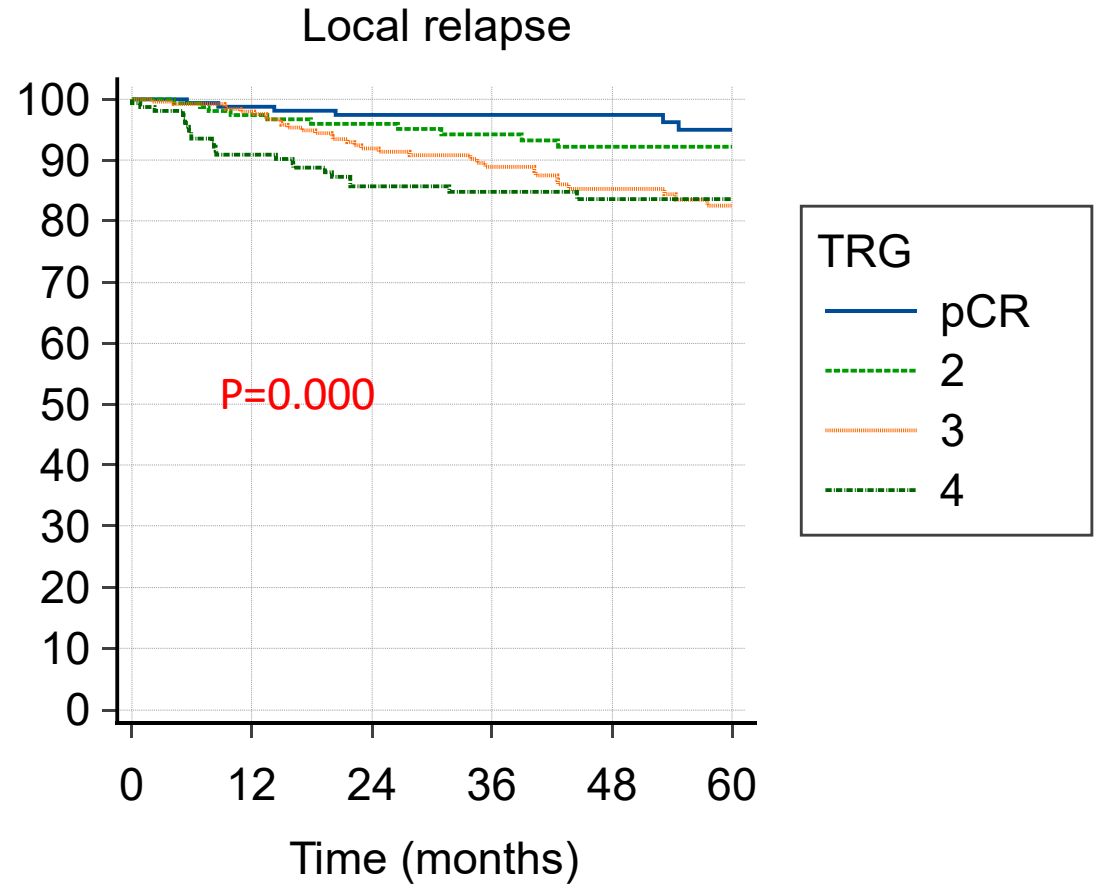
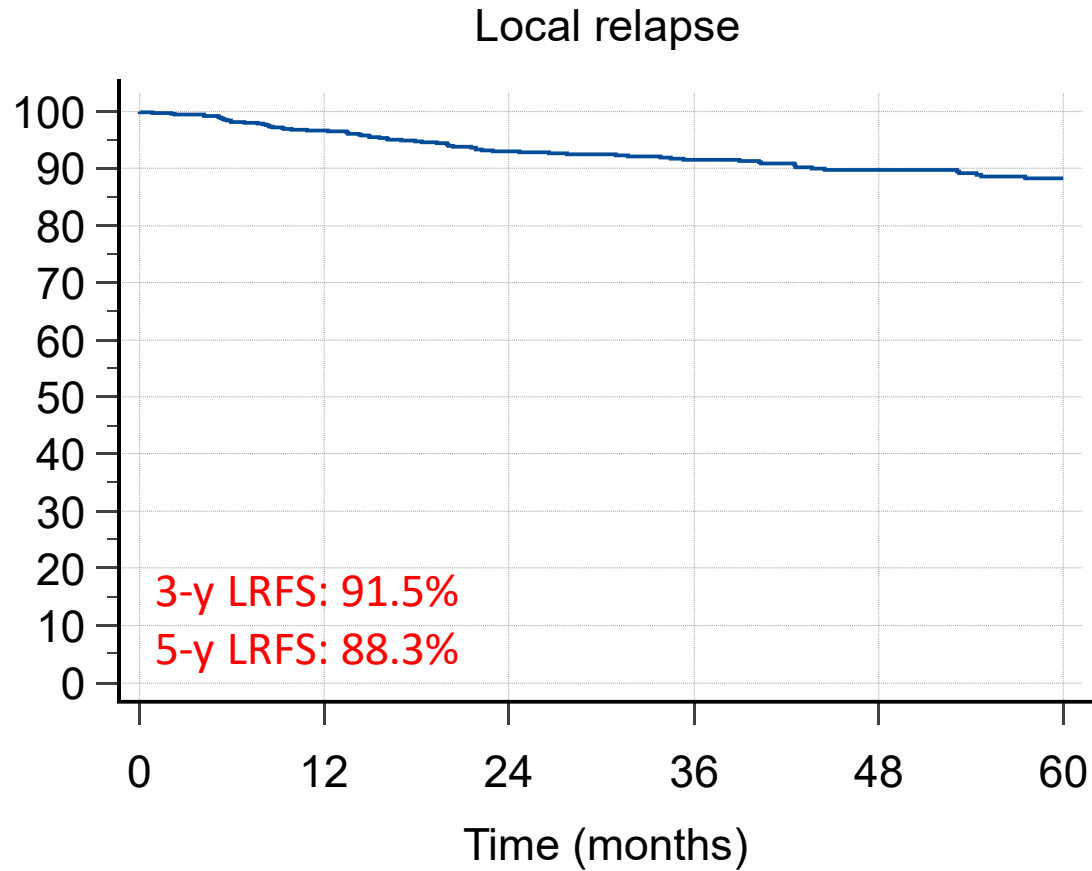
798 pts
P=0.0042



121 pts
P=0.000

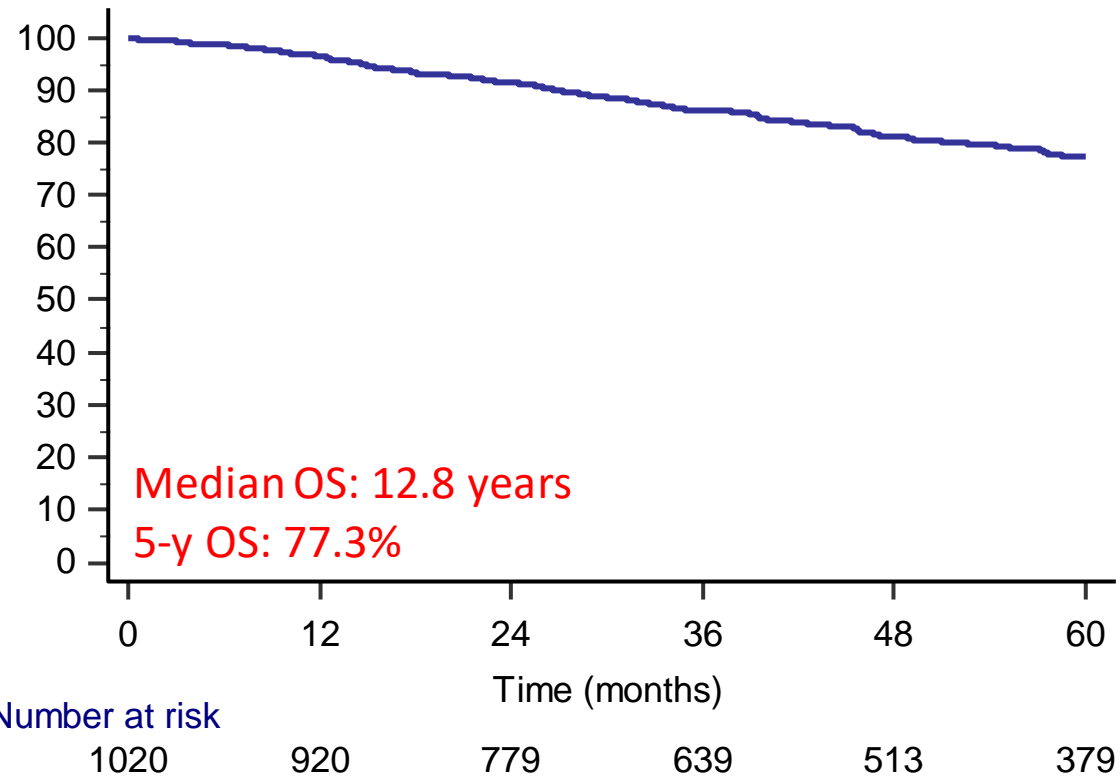


Results

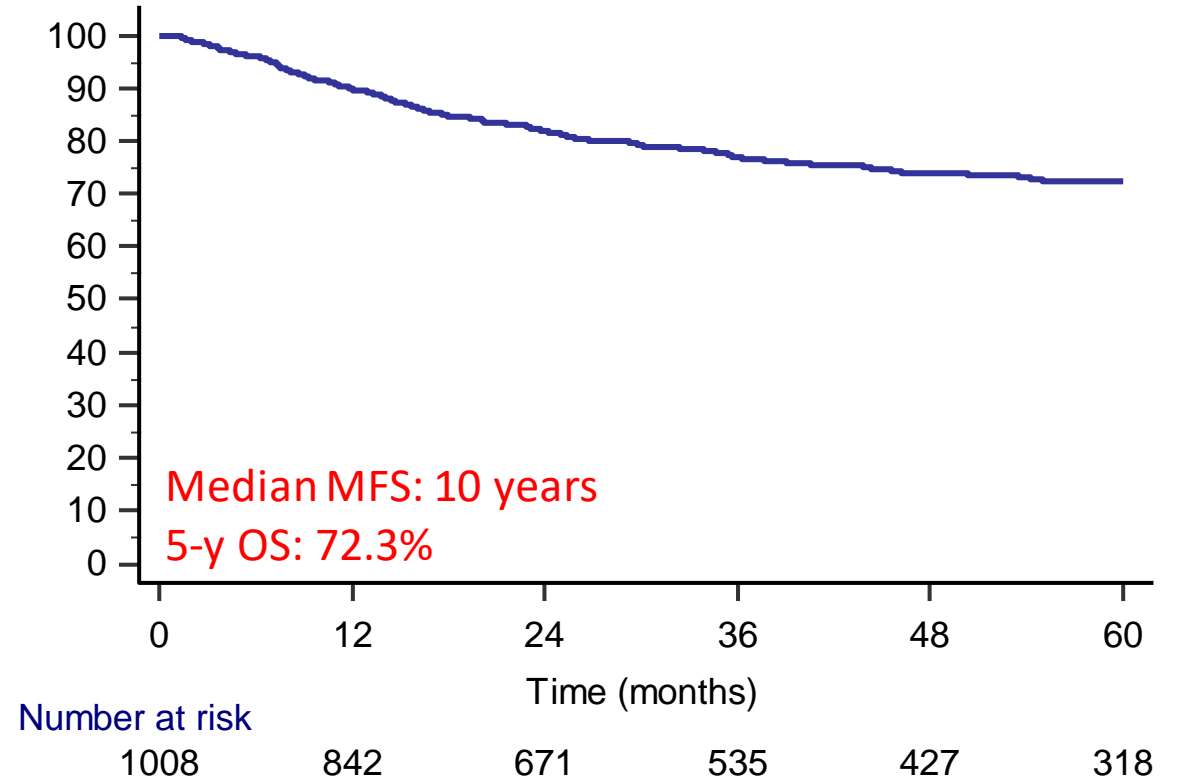


Results

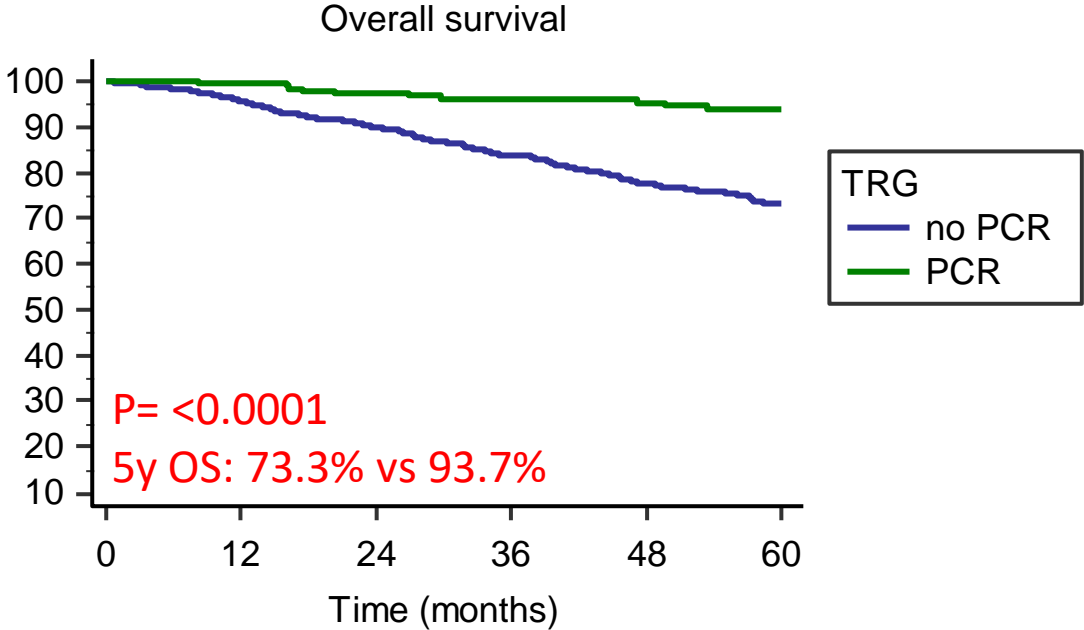
Overall survival



Metastases-free survival

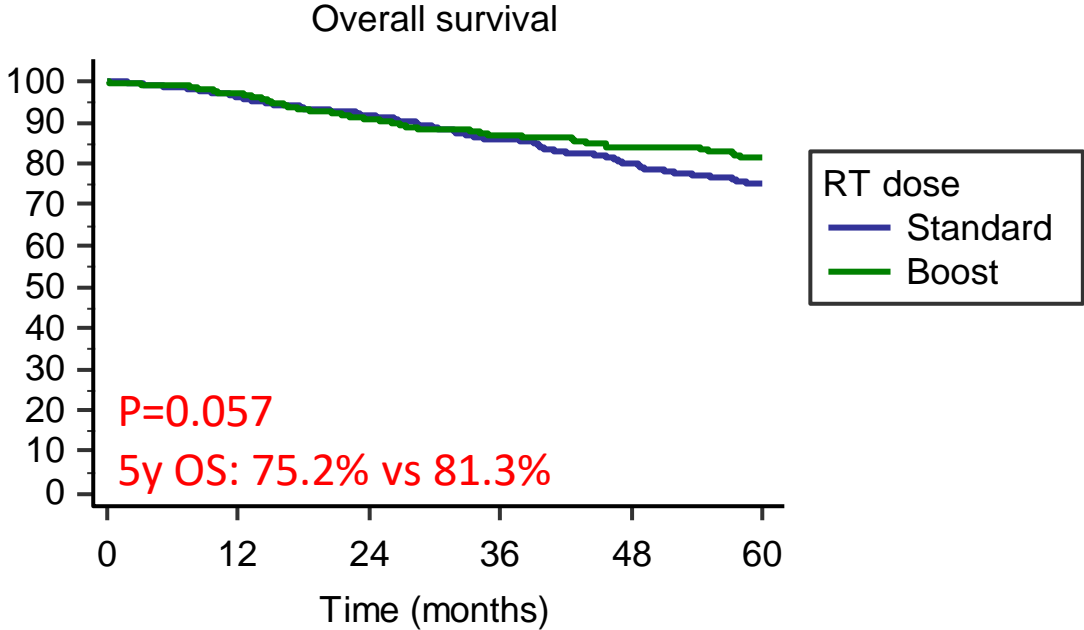


Results



Number at risk

Group: no PCR	0	12	24	36	48	60
812	729	608	491	389	288	
Group: PCR	208	191	171	148	124	91

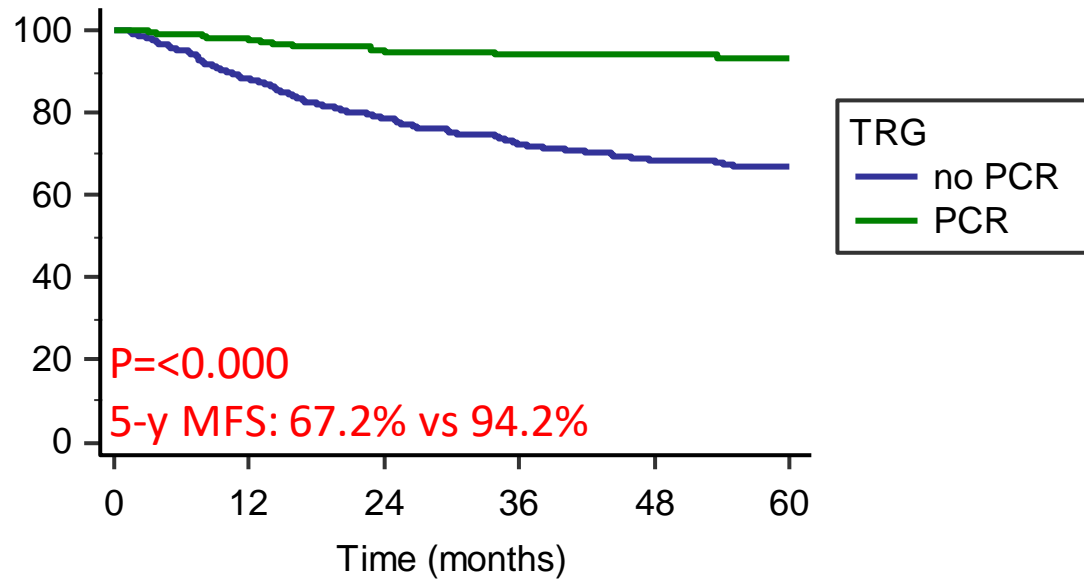


Number at risk

Group: Standard	0	12	24	36	48	60
658	584	500	398	320	228	
Group: Boost	362	336	279	241	193	151

Results

Metastases-free survival



Number at risk

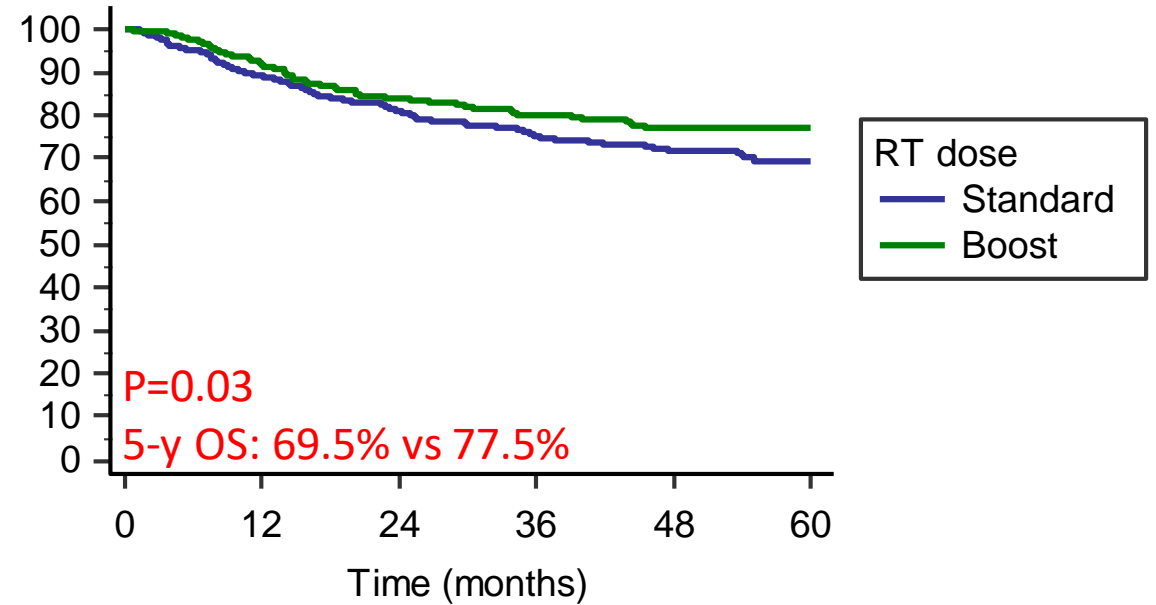
Group: no PCR

802	651	503	393	307	232
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Group: PCR

206	191	168	142	120	86
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Metastases-free survival



Number at risk

Group: Standard

647	531	419	325	258	180
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Group: Boost

361	311	252	210	169	138
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Conclusion

- Finalize analysis (expec. February 2024)
- Submission to Journal (expec. April 2024)

Thanks to all Centers!

Contact: luca.nicosia@sacrocuore.it