RetrY

Radiotherapy & Tnt for Recurrent rectal cancer in previouslY irradiated patients, an AIRO-GI platform:

A multicenter prospective observational study

Gemelli
Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Università Cattolica del Sacro Cuore
ART
Advanced Radiation Therapy

Background

- Incidence: 4-8%

- Multimodal treatment
  Surgery± RT (CRT-SBRT-CIRT) ± CHT

- Patient stratification

Hypothesis

RT in all its types followed by consolidation CHT for LRRC, in patients previously irradiated to the pelvis, is an effective method to increase patient survival by increasing LC, i.e. to demonstrate how the combination of CHT with re-RT in LRRC patients can lead to improved LC.

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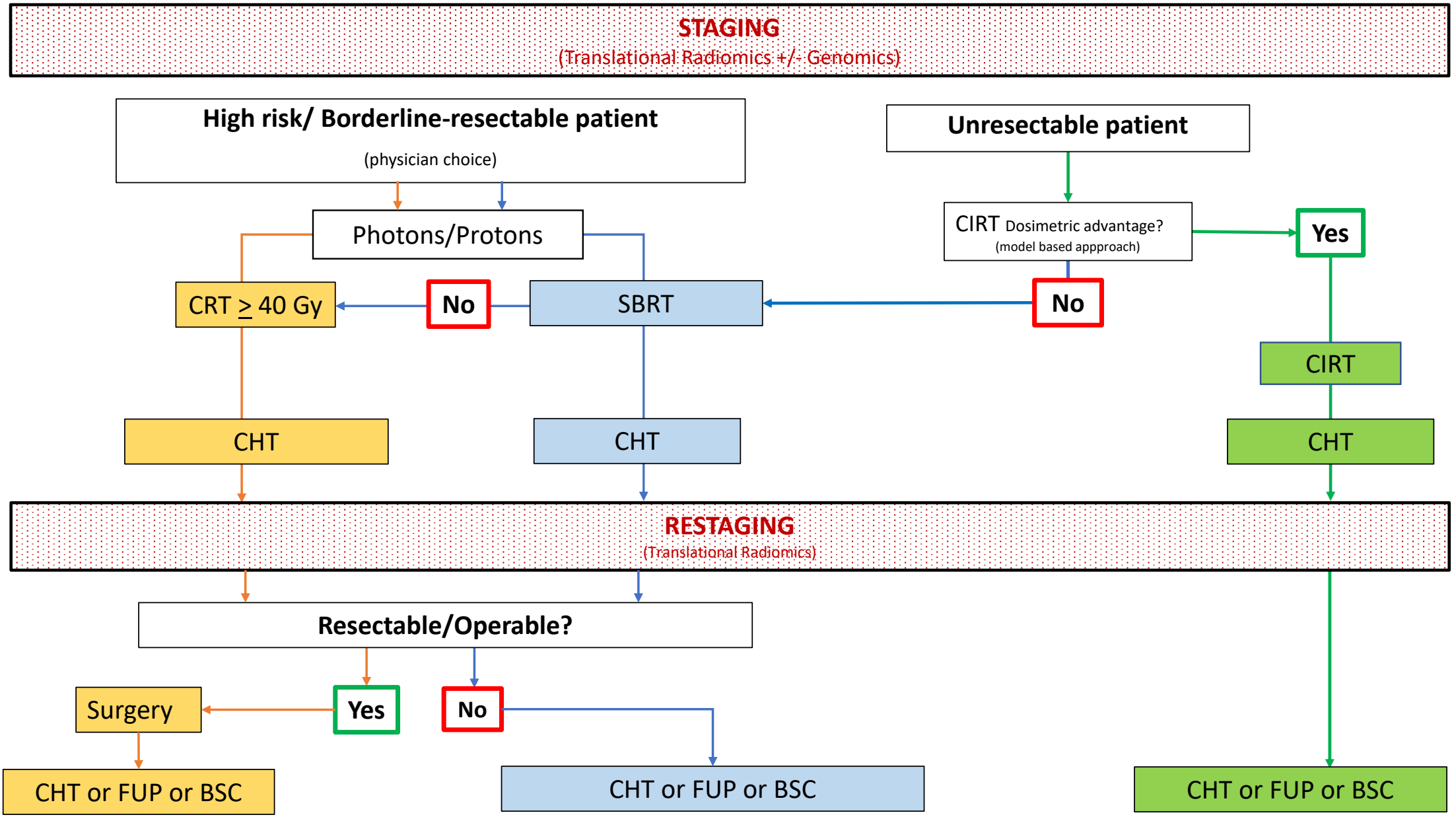
STAGING
(Translational Radiomics +/- Genomics)
High risk/ Borderline-resectable patient
(physician choice)
Unresectable patient
Photons/Protons
CIRT Dosimetric advantage?
(model based appproach)
Yes
CRT ≥ 40 Gy
No
SBRT
No
CIRT
CHT
CHT
CHT
RESTAGING
(Translational Radiomics)
Resectable/Operable?
Surgery
Yes
No
CHT or FUP or BSC
CHT or FUP or BSC
CHT or FUP or BSC

Study design

Multicenter prospective observational study

General population inclusion criteria

- Age ≥ 18 years old
- ECOG 0-1
- Potentially curable oligometastatic disease
- Life expectancy of more than 24 months
- Potentially curable oligometastatic disease
- Histologically (if feasible) or radiologically proven pelvic LRRC
- Previous pelvic irradiation > 6 months
- Availability of the previous treatment plan in DICOM format only
- Signed written informed consent

Study design

Multicenter prospective observational study

Study duration and setting

- Italian centers collaborating within the Italian AIRO group for gastrointestinal malignancies, specialized in the management of RC and LRRC.
- The study will run from the approval of the present protocol by the ethics committee of the coordinator center and the satellite centers and patients will be recruited for the following **3 years**.

Sample size

- The sample of patients to be enrolled is equal to **88 subjects**.

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End-points

	High-risk/borderline resectable	Unresectable
Primary	**3y LC**	
Secondary	R0-Resection Rate (#R0 resection/total of patients)	
	R0-R1 RR (# R0-R1 resection/total of patients)	
	Resectability Rate (# of resection/total of patients)	
	Response Rate (Partial Response Rate + Complete Response Rate)	
	Complete response (pCR, cCR)	
	Progression free survival	
	Overall survival	
	Metastases free survival	
	Bleeding control (rate and time)	
	Pain control (rate and time)	
	Toxicity (acute and late; CTCAE v.05)	
	Quality of life (EORTC QlQ C30, CR 29)	

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Therapy

RT prescription

IMRT/VMAT (Protons/Photons):
PTV: 40-50 IN 1.8-2 Gy/fx

SBRT (Protons/Photons)

PTV: 35-40 Gy in 7-8 Gy/fx

CIRT
40 -60 Gy [RBE] in 3-4.8 Gy/fx 4 or 5 fxs per week

Concomitant CHT

5-fluorouracil (protracted intravenous infusion, 225 mg/m^2/day, 7 days per week)
or **Capecitabine** 1650mg/m^2/die 5 days per week or
Capecitabine 825mg/m^2/die, bid
+/- 4 cycles **Oxaliplatin** (50 mg/m^2), according to medical judgement.

If SBRT or CIRT, no concomitant CHT will be considered.

Surgery

At 12-13 weeks from the start of CRT, patients will be evaluated for tumor resectability, and, when feasible, surgical resection of recurrence will be performed no more than 2 weeks later.

Adiuvant CHT

According to the single Center.
At least 3 cycles, according to FOLFOX6 or de Gramont scheme.

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Where we are

Protocol approved CE (Policlinico Gemelli) on 16/05/2023

… Registration on clinicaltrial.gov in progress

Writing commettee

- Prof Gambacorta **(PI)**
- Dr Alterio
- Dr Caravatta
- Dr Macchia
- Dr Mantello
- Dr Romano
- Dr Valvo
- Dr Vitolo

Review commettee

- Dr Lupattelli
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- Prof Pergolizzi
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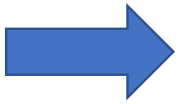
Advisory commette

- Prof Valentini
- Dr De Paoli

Info



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