SCARLET- Italian proSpeCtive observAtional Register on treatments for rEcTal cancer pT1

Giuditta Chiloiro

Fondazione Policlinico Universitario "A. Gemelli" IRCCS, Roma

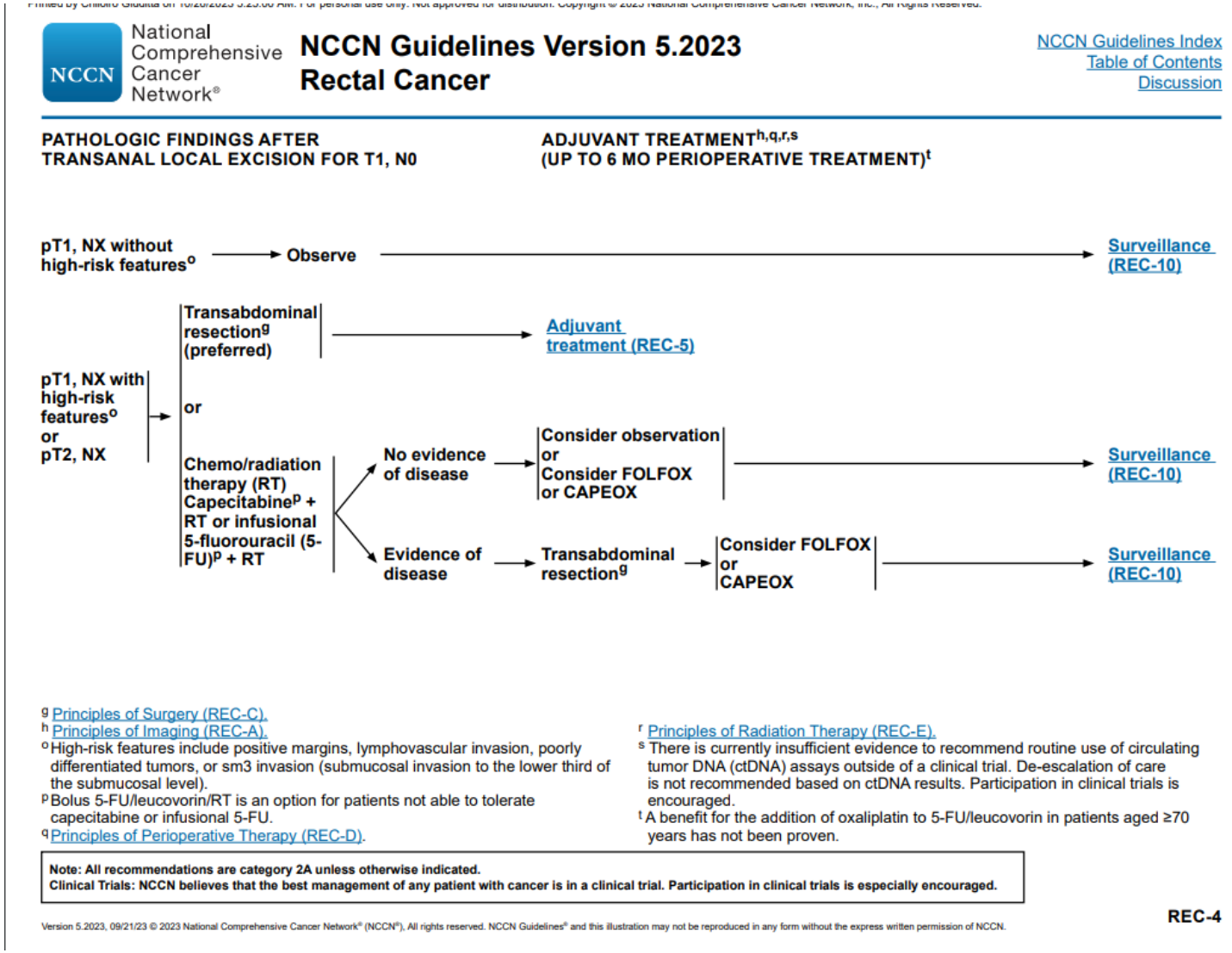
Background

I programmi di screening organizzati hanno permesso la diagnosi precoce in pazienti asintomatici portando la percentuale di casi con **carcinoma del retto in fase iniziale dal 8% al 30%**

Background

pT1 con fattori di rischio high→

rischio di recidiva locale e linfonodale ≈ **20%**



National Comprehensive Cancer Network®

NCCN Guidelines Version 5.2023
Rectal Cancer

NCCN Guidelines Index
Table of Contents
Discussion

PATHOLOGIC FINDINGS AFTER TRANSANAL LOCAL EXCISION FOR T1, N0

ADJUVANT TREATMENT[h,q,r,s] (UP TO 6 MO PERIOPERATIVE TREATMENT)[t]

[g] Principles of Surgery (REC-C).
[h] Principles of Imaging (REC-A).
[o] High-risk features include positive margins, lymphovascular invasion, poorly differentiated tumors, or sm3 invasion (submucosal invasion to the lower third of the submucosal level).
[p] Bolus 5-FU/leucovorin/RT is an option for patients not able to tolerate capecitabine or infusional 5-FU.
[q] Principles of Perioperative Therapy (REC-D).
[r] Principles of Radiation Therapy (REC-E).
[s] There is currently insufficient evidence to recommend routine use of circulating tumor DNA (ctDNA) assays outside of a clinical trial. De-escalation of care is not recommended based on ctDNA results. Participation in clinical trials is encouraged.
[t] A benefit for the addition of oxaliplatin to 5-FU/leucovorin in patients aged ≥70 years has not been proven.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

Background

- 31 pT1 at least 1 rsk factor, underwent RT-CT

- Median follow-up 51 months:

  - 3yLC: 87%→ underwent savage surgery
  - 3yDFS 73%
  - 3yOS 92%

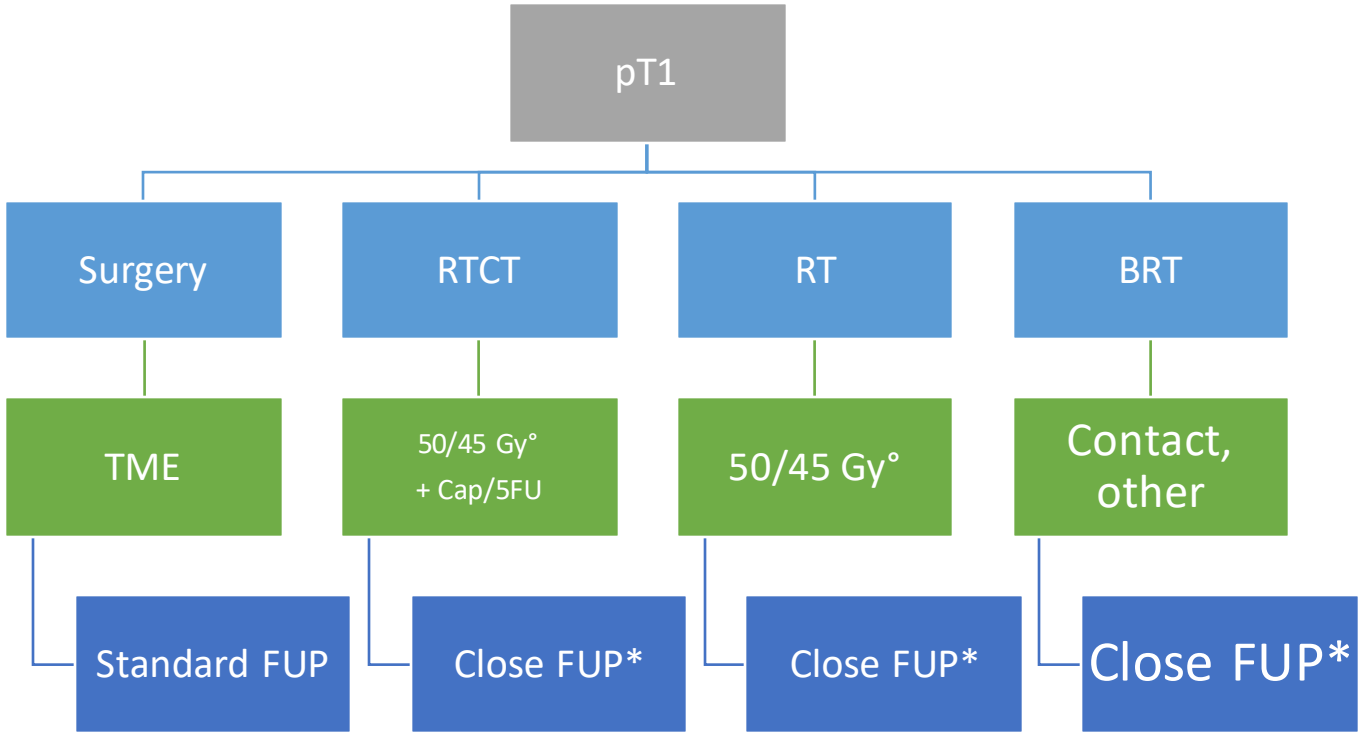
INCLUSION CRITERIA

Primary pT1 rectal adenocarcinomas undergoing local resection procedures (including EMR, ESD, transanal local resection, TAMIS, TEM) that meet one of the following features **CONFIRMED BY A CENTRAL READER (2nd look)**

- Poorly differentiated adenocarcinoma or mucinous adenocarcinoma or signet-ring cell carcinoma
- Pathological (submucosa invasion > 1000 microns)
- Lymphatic invasion positive or venous invasion positive (confirmed using immunostaining)
- Budding grade of 2-3

- **REFUSED SURGERY**

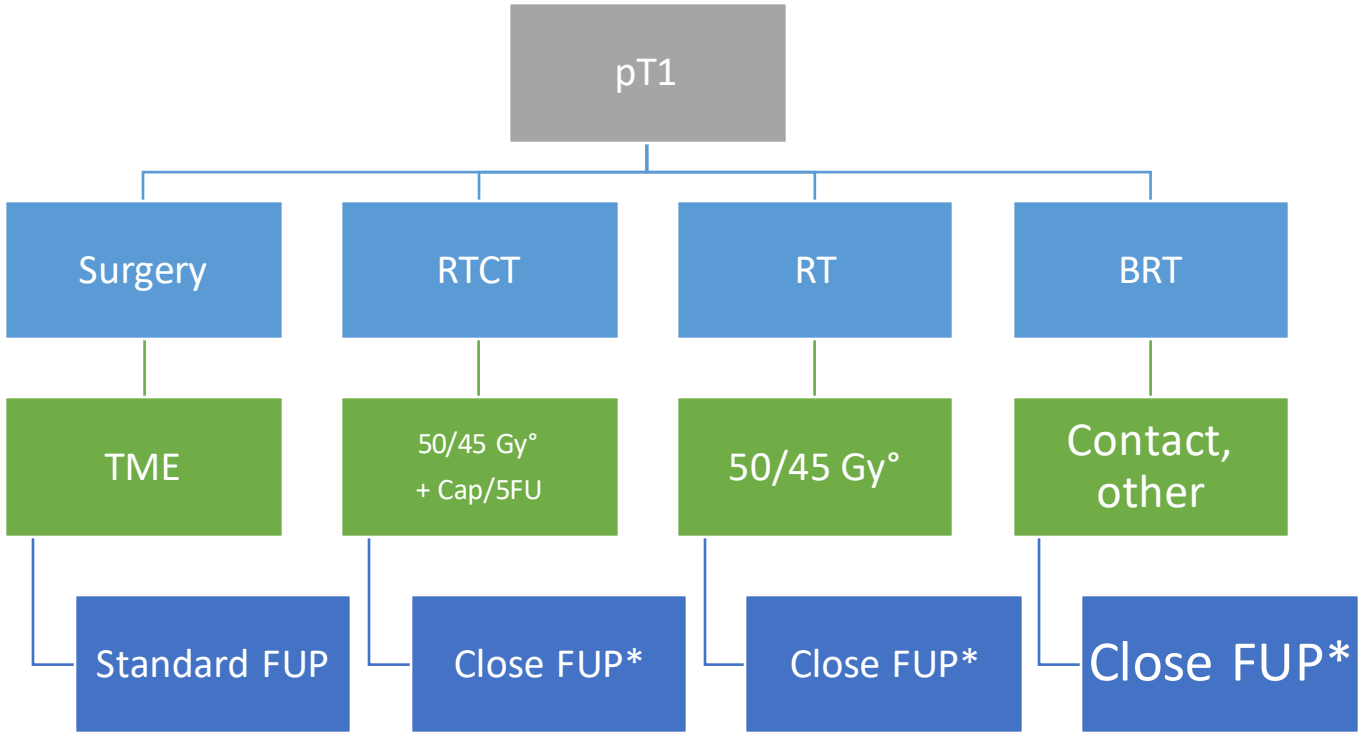
Flowchart- Scarlet



Studio:

- Prospettico
- Osservazionale
- Multicentrico

Flowchart- Scarlet



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RT fractionation:
CTV1: scar+ corresponding mesorectum in case of R1;
CTV2: whole mesorectum, presacral space and posterior lateral nodes.
PTV1 and PTV2 are obtained from CTV1 and CTV2 with 0.7 cm margin.
The prescribed dose at PTV2 will be 45 Gy and to PTV1 50 Gy
Concomitant CT: 5-FU (225 mg/mq/day in continuous infusion) or oral capecitabine (1650 mg/mq/day chronomodulated).

***Close follow-up:** Rectoscopy, DRE and clinical examination every 3 months for the first 2 years, then every 6 months for the next 3 years, colonoscopy after 1 and 3 years. MRI of the pelvis every 6 months and CT of the chest, abdomen and pelvis every year.

Follow-up Scarlet

Mese	3	6	9	12	15	18	21	24	30	36	42	48	54	60
Es. obiettivo	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Es. ematoch. + CEA	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Rettoscopia	X	X	X	X	X	X	X	X	X	X	X	X	X	X
RM pelvica		X		X		X		X		X		X		X
TC torace-addome				X				X		X		X		X
Colonscopia				X								(X)		

Objectives

Primary aim

- 1,3 and 5 y DFS and 1, 3 and 5y OFS
- Overal Serious Adverse Events (SAEs)

Secondary aim

- TME free survival
- OS
- QoL
- Colonoscopy free survival

Prossimi step

- Writing Committee / Reviewing Committee
- Endorsement **AIRO SICO SIGE**
- Approvazione CE
- Survey sulla gestione del pT1

giuditta.chiloiro@policlinicogemelli.it