
XXXIII CONGRESSO NAZIONALE AIRO
AIRO2023
BOLOGNA,
27-29 OTTOBRE 2023
PALAZZO DEI CONGRESSI
Radioterapia Oncologica: l'evoluzione al servizio dei pazienti
Associazione Italiana
Radioterapia e Oncologia clinica

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Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

Adjuvant stereotactic pancreatic radiotherapy (SPARTA trial): preliminary toxicity results of an ongoing phase II single center prospective study (NCT05043857)

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No conflicts of interest to declare

Background

Pancreatic cancer (PC) is expected to become in the next 10 years the **second cause of cancer-related mortality**

Rahib et al; Cancer Res 74(11) 2913–21; 2014

Resection is the only treatment associated with the long-term survival, but **70%** of resected patients develop **distant metastases** within 2 years of surgery

Siegel et al; Ca Cancer J Clin 71:7–33; 2021

Approximately **30% of patients** with resected PC experience **isolated local recurrence**, confirmed by autopsy studies

Iacobuzio-Donahue et al; J Clin Oncol 27:1806-1813; 2009

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Adjuvant chemoradiation (CRT)

Surgery
Adjuvant chemotherapy

- Long treatment time (6 weeks) may allow for tumor repopulation and may delay the start of more effective chemotherapy, increasing the **risk of distant metastasis**

- A low radiation dose, due to potential toxicity, could **reduce the local control rate**

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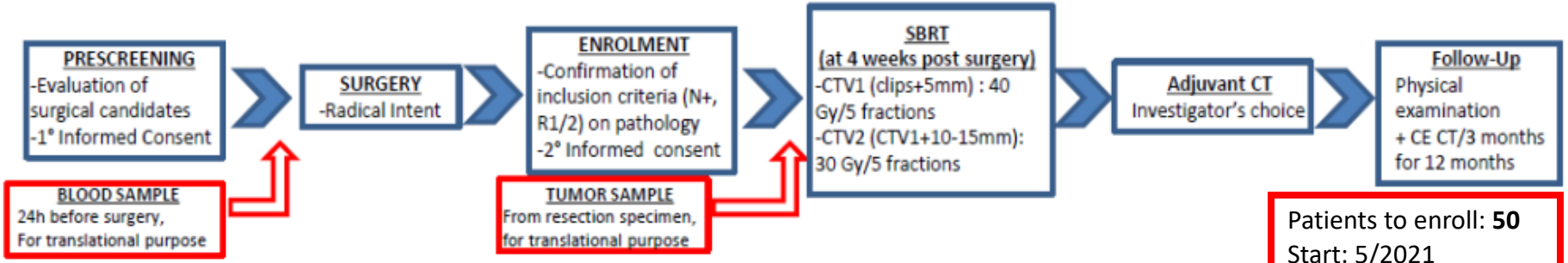
Stereotactic PAncreatic RadioTherapy Adjuvant therapy (SPARTA)

Surgery
Adjuvant chemotherapy

A phase II prospective open-label trial assessing the impact of adjuvant SBRT following surgical resection of pancreatic cancer with high risk features



Patients to enroll: **50**
Start: 5/2021
Duration: 3+1 years

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Inclusion criteria

- Surgically treated T1-T4 ADK with or without prior chemotherapy
  AND
  -close (<2.5mm)/positive resection margin
  AND/OR
  -N1 at lymphadenectomy
- ECOG PS <2

Exclusion criteria

- Metastatic disease
- Biliary tract or neuroendocrine tumors
- History of malignancies except for non-melanoma cutaneous tumors

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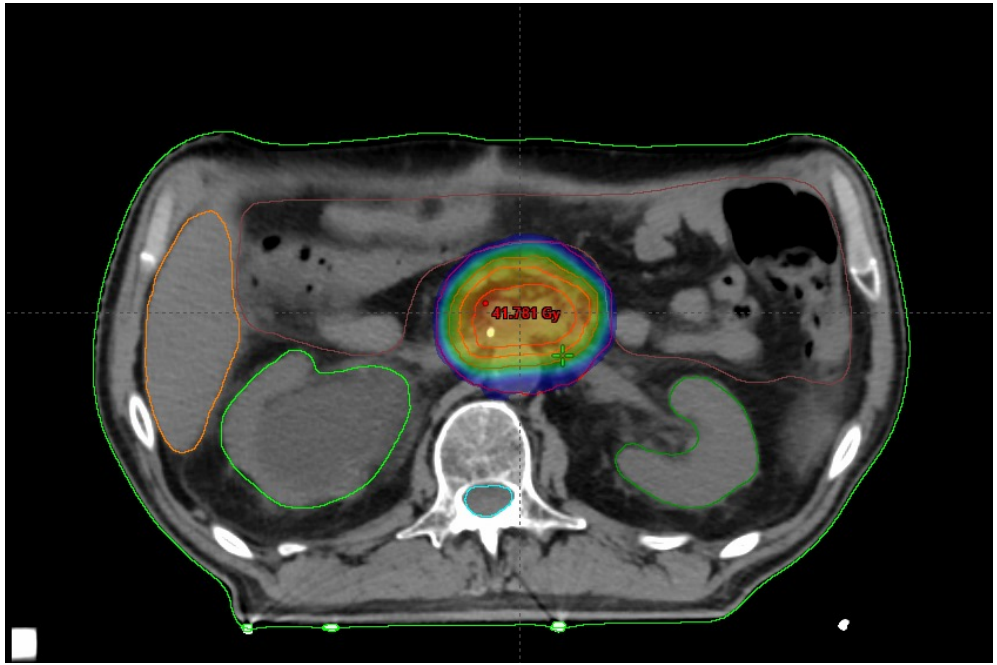
SBRT

2 volumes in **5 fractions**:

- CTV1 (**40 Gy**) which covers clips + isotropic 5mm expansion

- CTV2 (**30 Gy**) which covers CTV1+ anisotropic 10-15 mm expansion +
  - corresponding vessels
  - retroperitoneum posterior to the SMV/SMA or celiac axis



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Primary endpoint

- Local control

Secondary endpoints

- Disease-free survival
- Overall survival
- Patterns of failure
- **Acute and late toxicity according to CTCAE v.5.0**
- Evaluation of clinical-pathological factors related to disease recurrence

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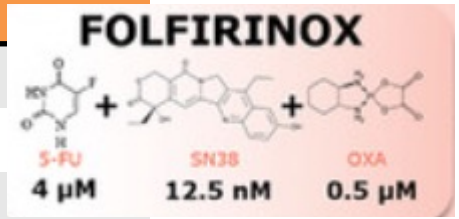
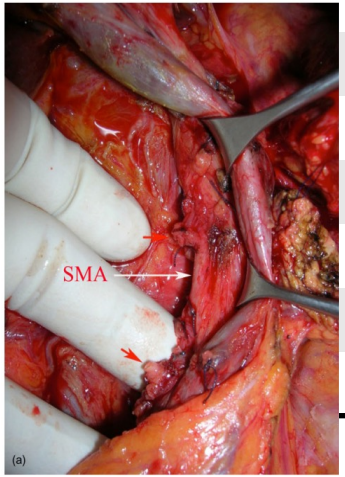
Main characteristichs	42 enrolled patients N° of patients, %
Chemotherapy (ChT)	
• Neoadjuvant ChT	19, 45.2%
• Adjuvant ChT	18, 42.8%
Surgery	
• Pancreatoduodenectomy	24 , 57%
• Distal pancreatectomy	11, 26%
• Total pancreatectomy	7, 16.6%
Main high risk features	
• R1	38, 90.4%
• N+	21, 50%





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42 enrolled patients

Main toxicities during SBRT

- Asthenia (11.9%)
- Nausea (23.7%)
- Abdominal pain (14.3%)
- Diarrhea (14.3%)

No patients experienced G3 toxicity

	Grade 1 N° of patients (%)	***Grade 2*** N° of patients (%)
During radiotherapy		
Asthenia	5 (11.9%)	
Nausea	6 (14.2%)	4 (9.5%)
Vomiting	2 (4.7%)	
Dyspepsia	2 (4.7%)	
Abdominal pain	5 (11.9%)	1 (2.4%)
Bloating	1 (2.4%)	
Diarrhea	5 (11.9%)	1 (2.4%)

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42 enrolled patients

The most frequent toxicities ***after 3 and 6 months*** were:

- Abdominal pain (16,6%)
- Diarrhea (11.8%)

No patients experienced G3 toxicity

	Grade 1 N° of patients (%)	***Grade 2*** N° of patients (%)
Three months after radiotherapy		
Asthenia		1 (2.4%)
Nausea		
Vomiting		
Dyspepsia		
Abdominal pain	3 (7.1%)	
Bloating	1 (2.4%)	
Diarrhea	2 (4.7%)	
Six months after radiotherapy		
Asthenia		
Nausea		
Vomiting		
Dyspepsia		
Abdominal pain	3 (7.1%)	1 (2.4%)
Bloating		
Diarrhea	3 (7.1%)	
Malabsorption		1 (2.4%)

42 enrolled patients

The most frequent toxicities ***after one year*** were:

- Abdominal pain (4.7%)
- Diarrhea (2.4%)

After 6 and 12 months we observed due cases of G2 malabsorption returned after adjustment of pancrealipase therapy

No patients experienced G3 toxicity

	Grade 1 N° of patients (%)	***Grade 2*** N° of patients (%)
One year after radiotherapy		
Asthenia		
Nausea		
Vomiting		
Dyspepsia		
Abdominal pain		2 (4.7%)
Bloating		
Diarrhea	1 (2.4%)	
Malabsorption		1 (2.4%)

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Conclusions

- Adjuvant SBRT in PC proved to be a safe and well tolerated approach without ≥G3 toxicity
- We will await the final results to confirm these data

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