Multidisciplinary Approach to Rectal Cancer

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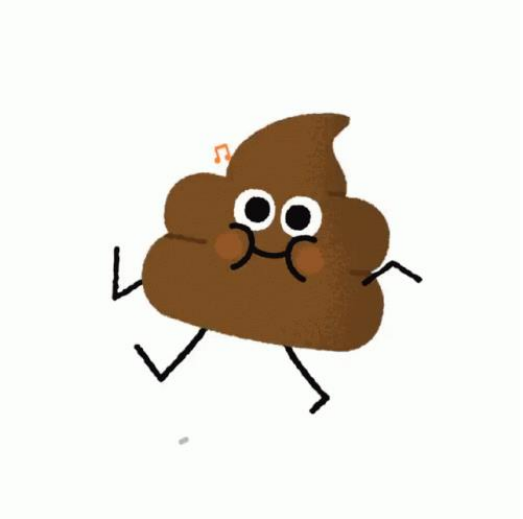
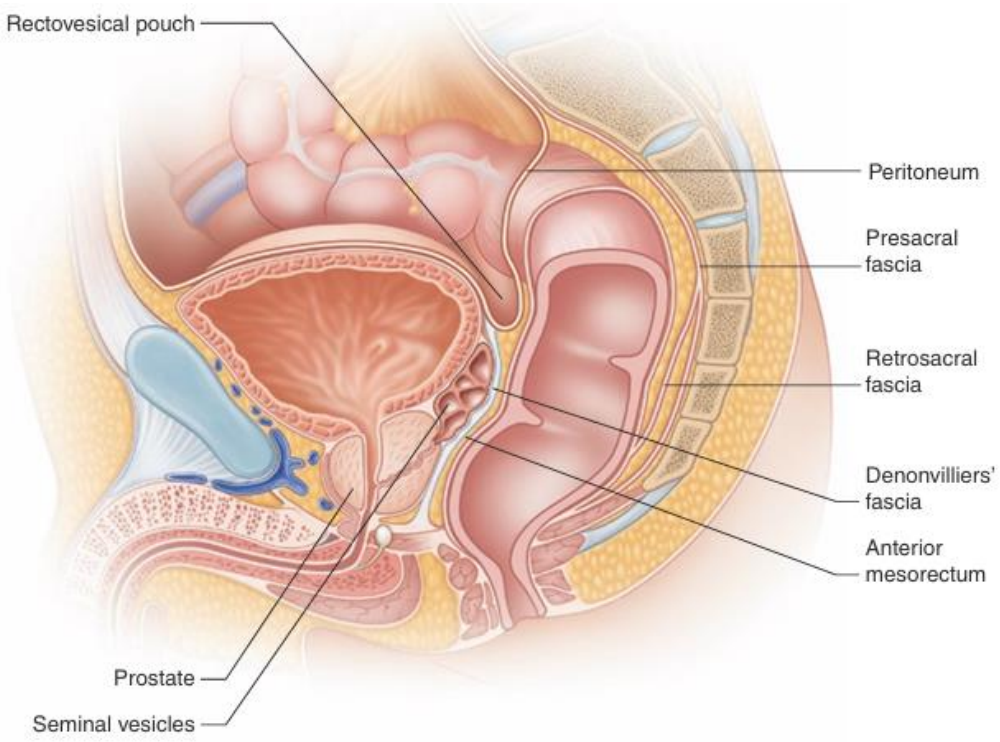
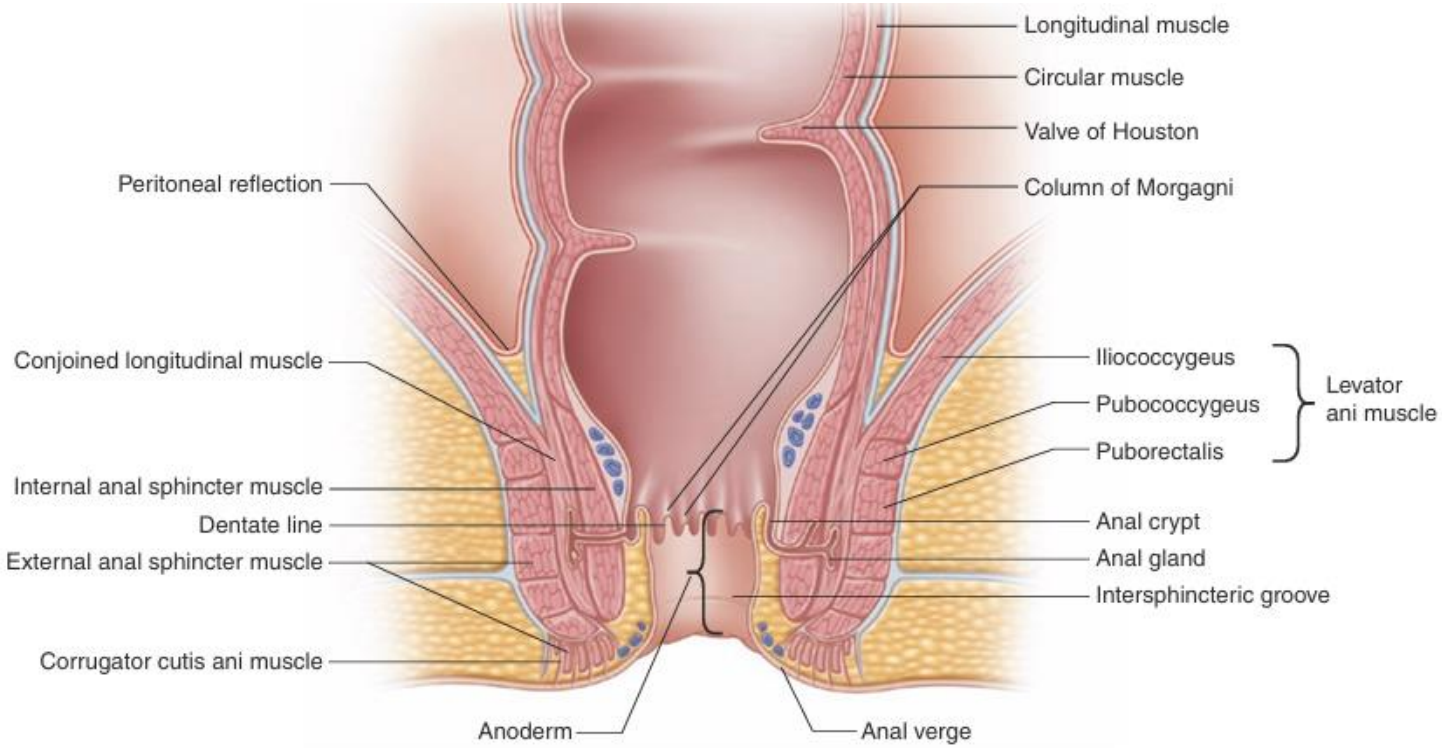
Rectal Cancer: Diagnosis, Staging, and Surgical Approach

SCOTT DOLEJS, MD MSC

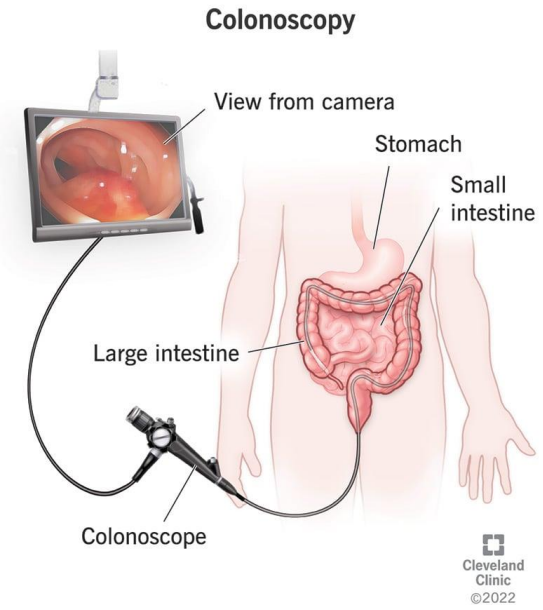


Anatomy of the Rectum





Diagnosis


Colonoscopy
View from camera
Stomach
Small intestine
Large intestine
Colonoscope
Cleveland Clinic
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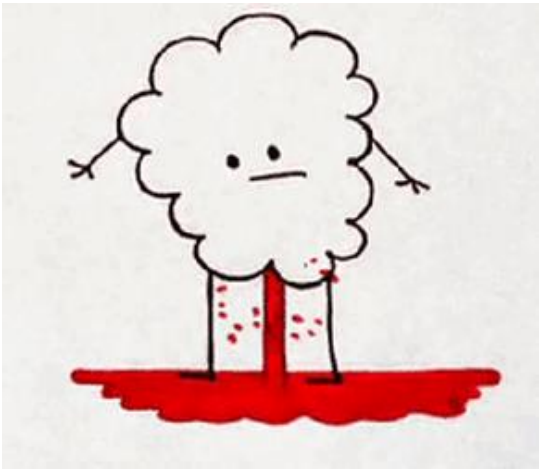

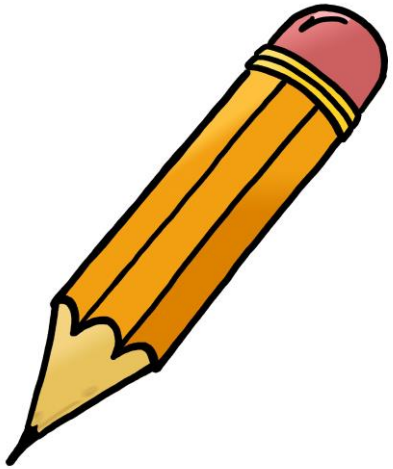

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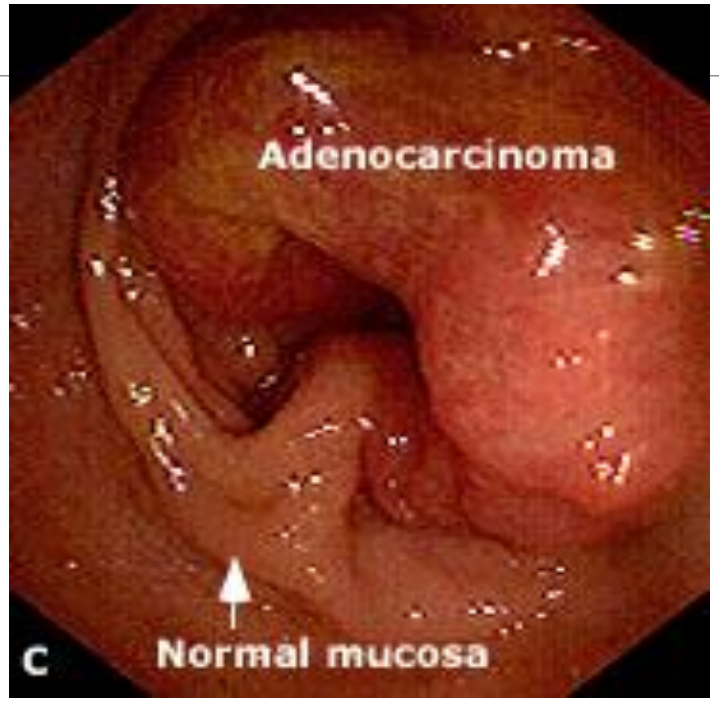
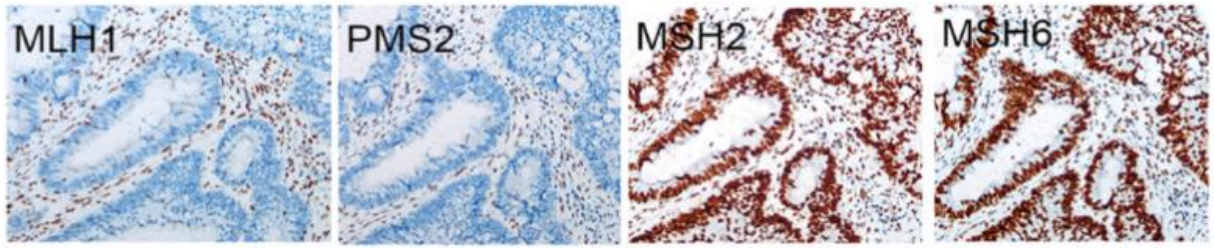
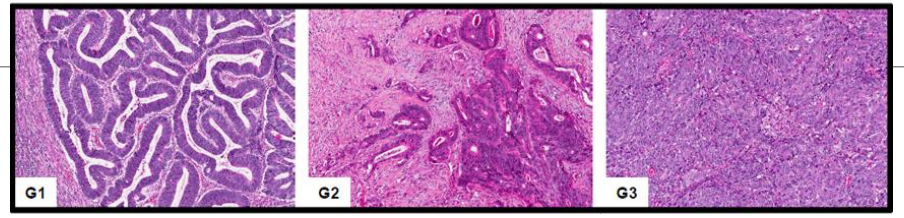
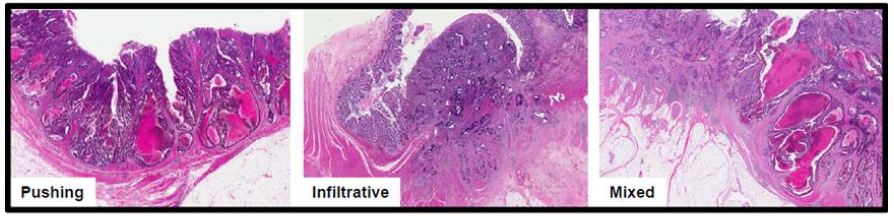




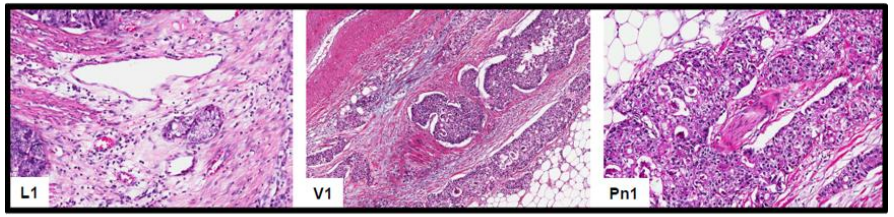
Tumor grade (100x)



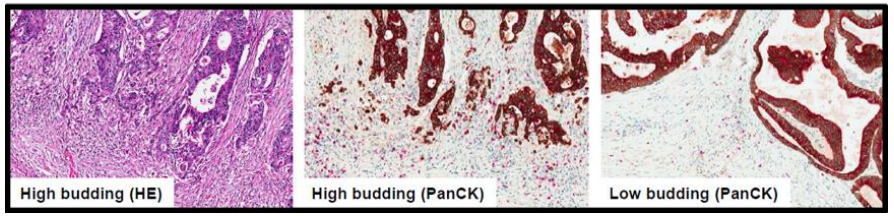
Tumor border configuration (10x)



Prognostic factors: Lymphovascular and perineural invasion (150x)



Additional prognostic factors: Tumor budding (150x)



Staging

American Joint Committee on Cancer (AJCC) TNM Staging Classification for Rectal Cancer 8th ed., 2017

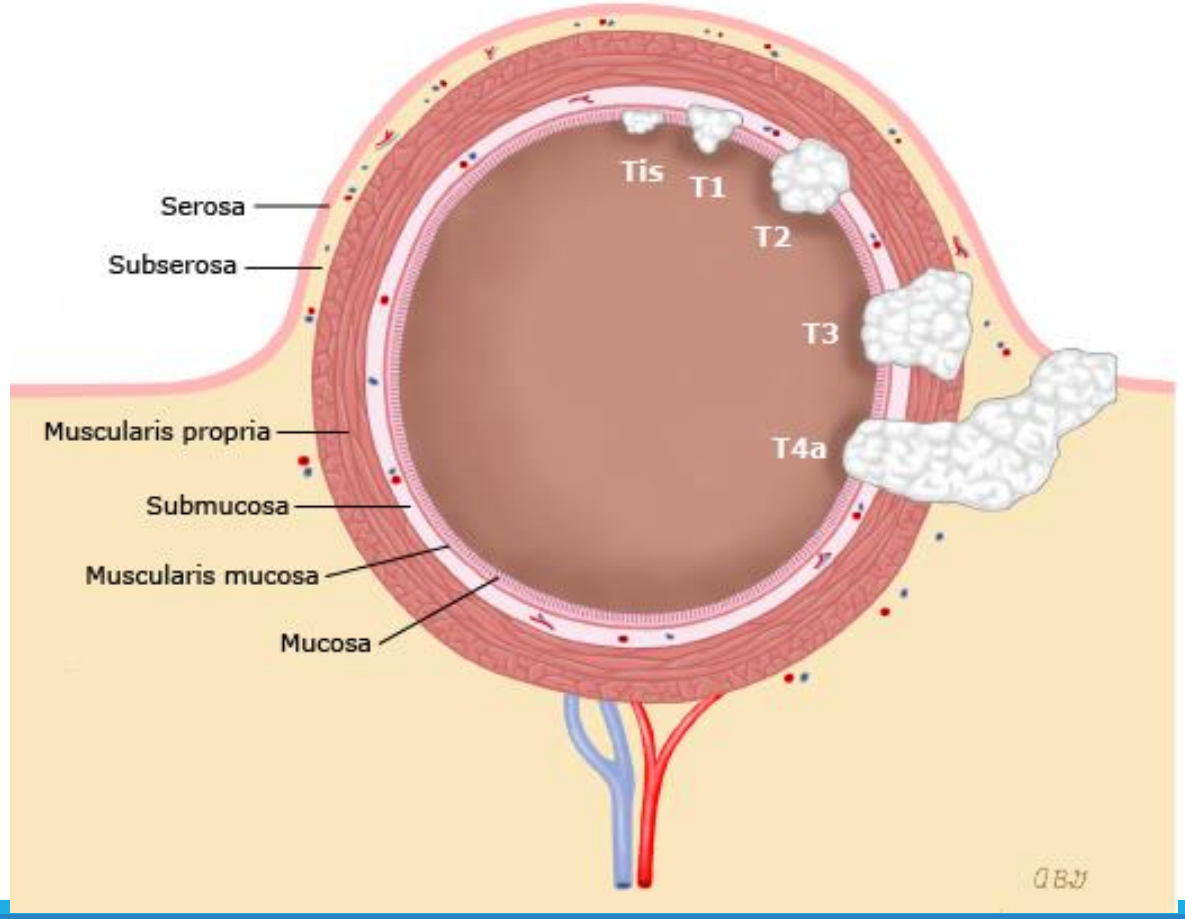
Table 1. **Definitions for T, N, M**

T	**Primary Tumor**
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma *in situ*: intramucosal carcinoma (involvement of lamina propria with no extension through muscularis mucosae)
T1	Tumor invades the submucosa (through the muscularis mucosa but not into the muscularis propria)
T2	Tumor invades the muscularis propria
T3	Tumor invades through the muscularis propria into pericolorectal tissues
T4	Tumor invades* the visceral peritoneum or invades or adheres** to adjacent organ or structure
T4a	Tumor invades* through the visceral peritoneum (including gross perforation of the bowel through tumor and continuous invasion of tumor through areas of inflammation to the surface of the visceral peritoneum)
T4b	Tumor directly invades* or adheres** to adjacent organs or structures

N	**Regional Lymph Nodes**
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	One to three regional lymph nodes are positive (tumor in lymph nodes measuring ≥0.2 mm), or any number of tumor deposits are present and all identifiable lymph nodes are negative
N1a	One regional lymph node is positive
N1b	Two or three regional lymph nodes are positive
N1c	No regional lymph nodes are positive, but there are tumor deposits in the subserosa, mesentery, or nonperitonealized pericolic, or perirectal/mesorectal tissues
N2	Four or more regional lymph nodes are positive
N2a	Four to six regional lymph nodes are positive
N2b	Seven or more regional lymph nodes are positive

M	**Distant Metastasis**
M0	No distant metastasis by imaging, etc.; no evidence of tumor in distant sites or organs. (This category is not assigned by pathologists)
M1	Metastasis to one or more distant sites or organs or peritoneal metastasis is identified
M1a	Metastasis to one site or organ is identified without peritoneal metastasis
M1b	Metastasis to two or more sites or organs is identified without peritoneal metastasis
M1c	Metastasis to the peritoneal surface is identified alone or with other site or organ metastases

Staging: T-Stage



Staging

Locoregional Extent of Disease:

- MRI
  - T1/2 vs T3/4: Sensitivity of 87% and Specificity of 71%
  - Lymph Node Involvement: Sensitivity 77% and Specificity of 71%
  - Circumferential Resection Margin Status: Sensitivity 77% and Specificity 94%
- Transrectal US
  - BETTER SENSITIVITY AND SPECIFICITY FOR T1, T2, T3, and T4 disease (in the 90% range)
  - Similar for lymph node involvement
  - CANNOT detect circumferential resection margin status

Metastatic Work-Up:

- CT chest/abdomen/pelvis
- CEA

Genetic Counseling and Genetic Panels

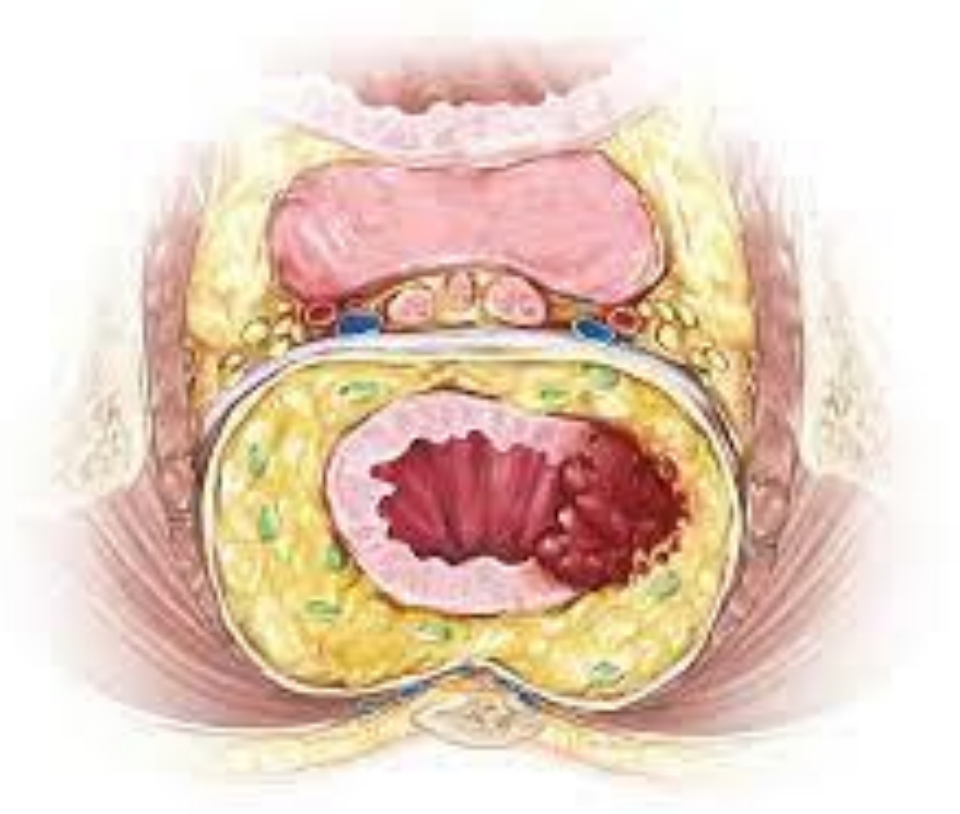
Changes in Treatment

Changes in Treatment

Pure resectional management, no anatomic planes, all abdominoperineal resections, tons of morbidity

- Rates of recurrence and morbidity

  dropped with holy plane
- Recurrence 15-45% to 7-10%

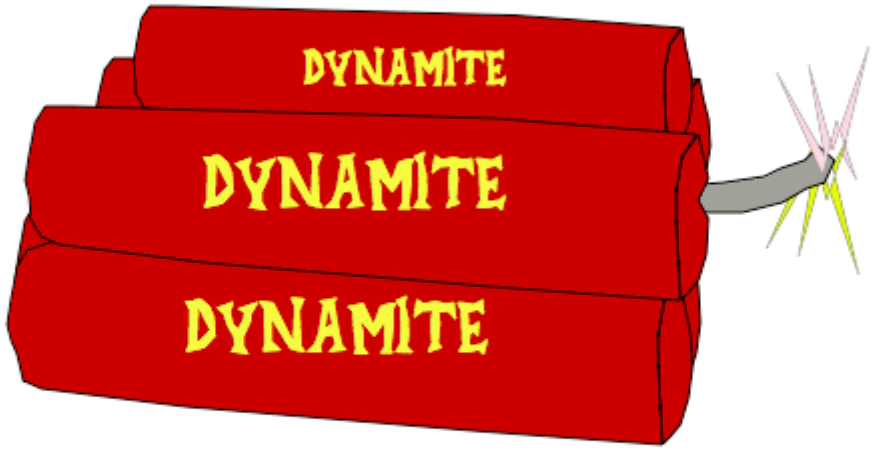


Changes in Treatment

Preoperative Radiation Therapy

- Preoperative RT compared to postoperative RT reduced risk of recurrence from 13% to 6% in German Rectal Cancer Study
- Preoperative RT versus good surgery in patients with T3 or N+ patients reduced risk of recurrence from 11% to 6% in Dutch TME trial
- Selective withholding of RT in recent PROSPECT trial

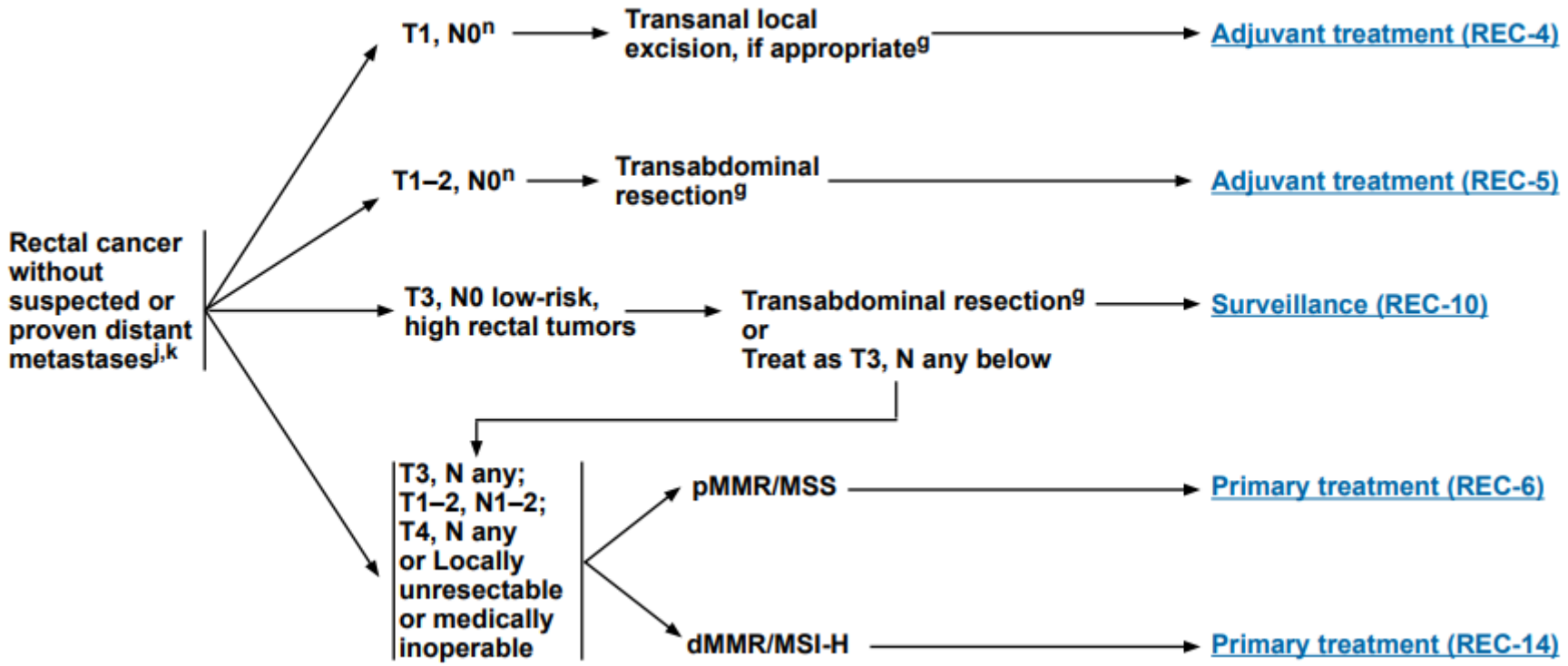
Changes in Treatment



Changes in Treatment

Surgical Approaches:

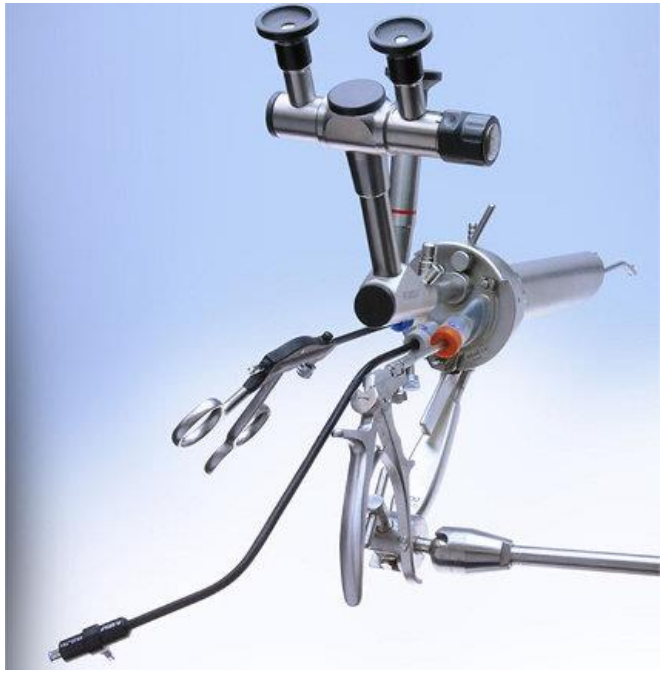
TAMIS, TEM, LAR, APR, DLI, WW

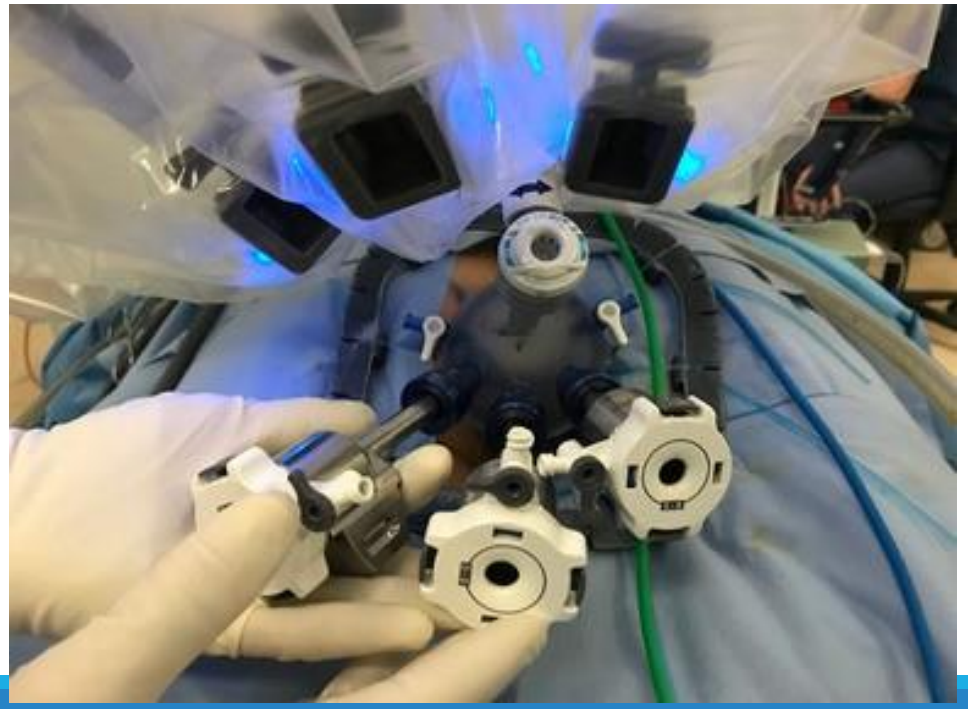


Surgical Approaches: TAMIS and TEM

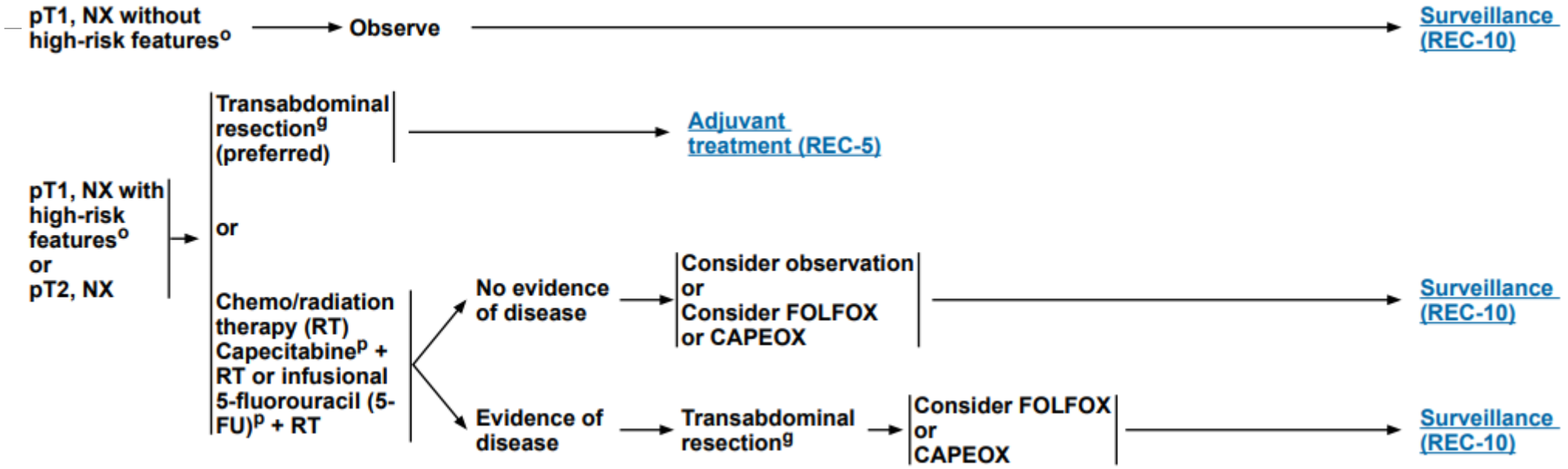
Transanal Minimally Invasive Surgery

Transanal Endoscopic Microsurgery



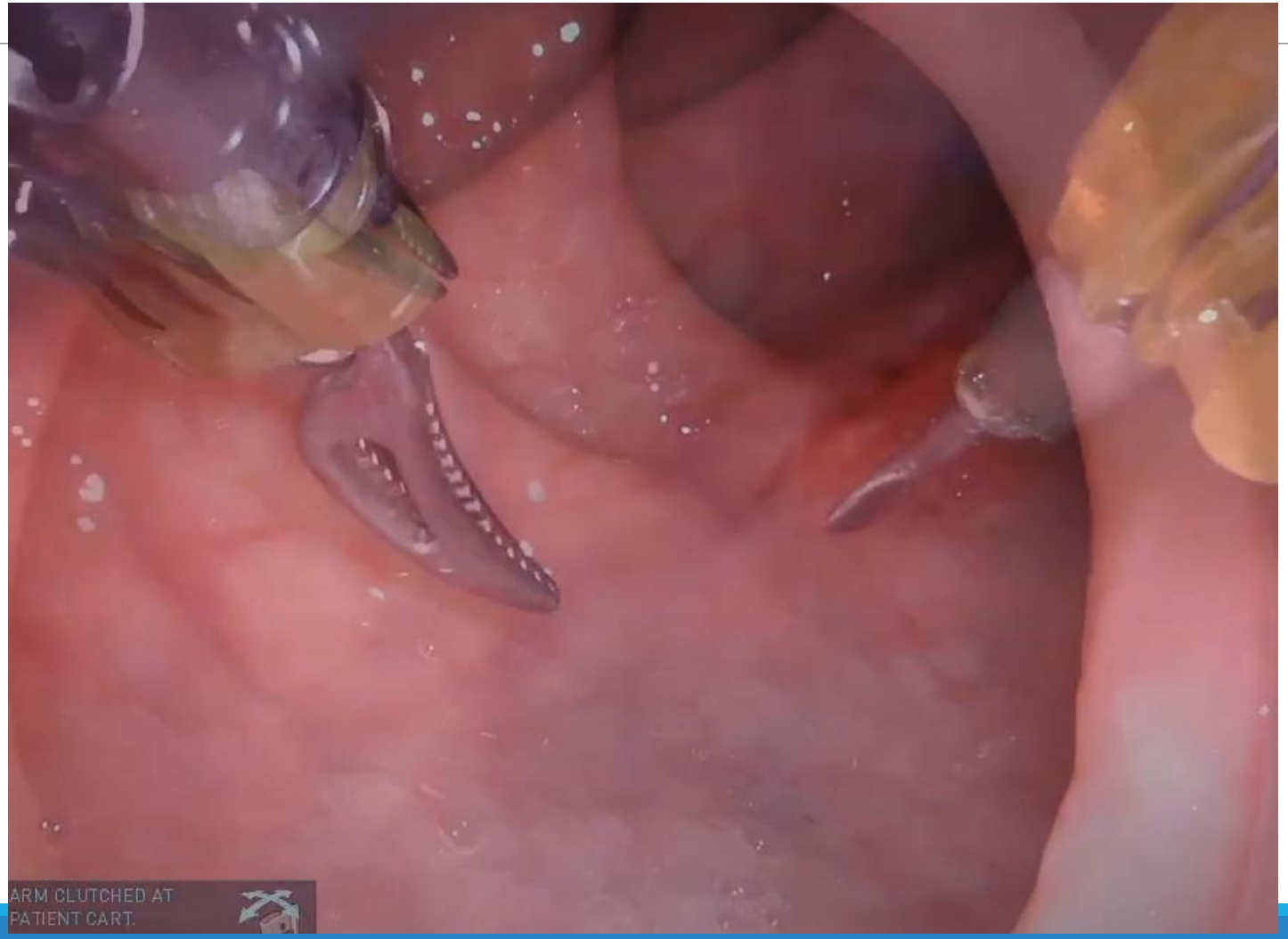


Surgical Approaches: TAMIS and TEM

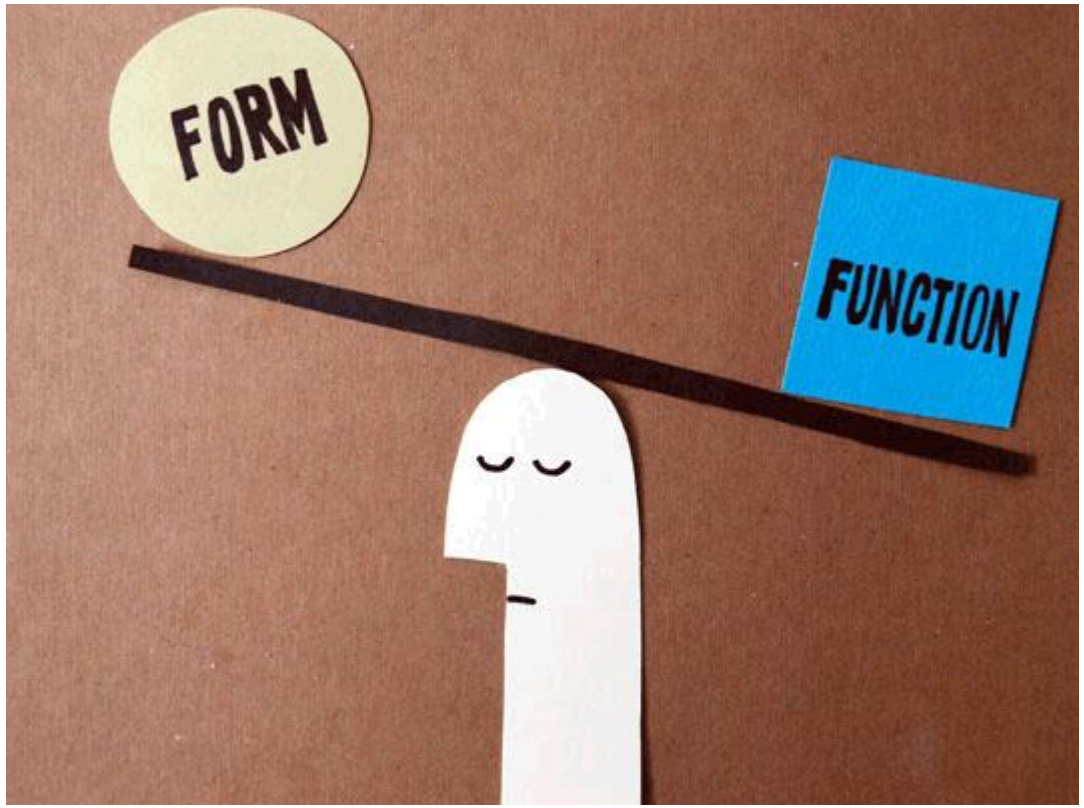


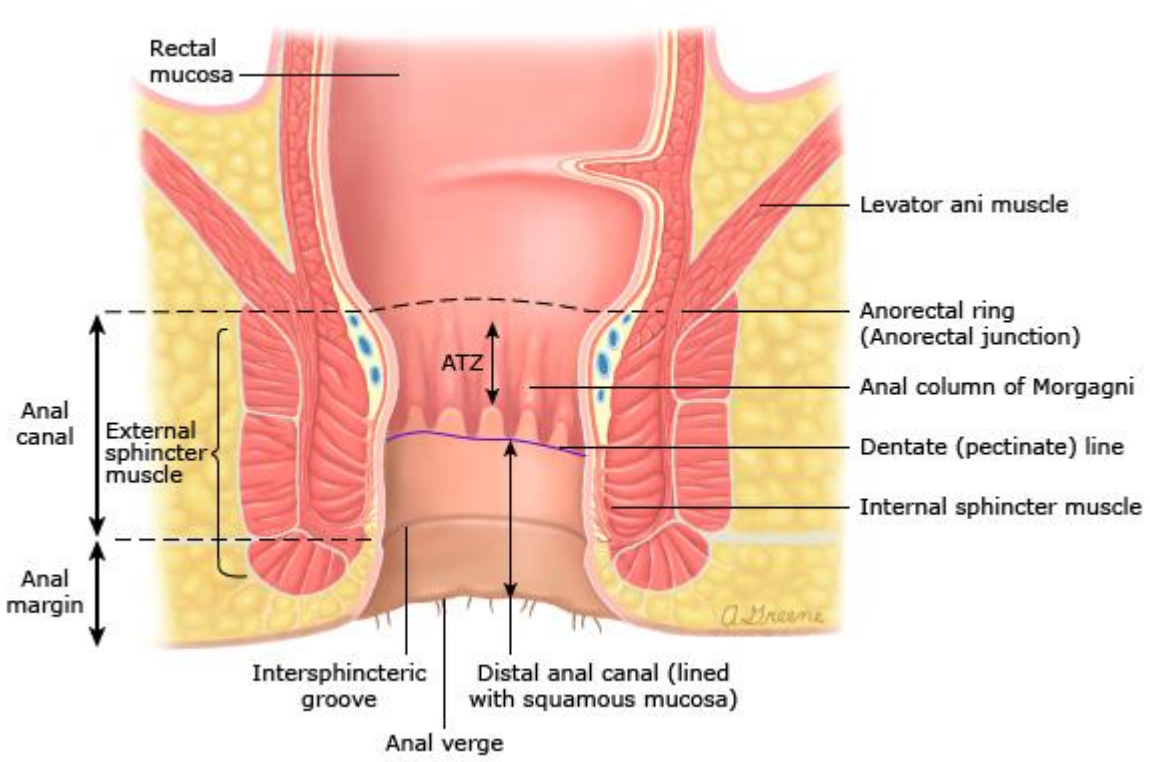
[o] High-risk features include positive margins, lymphovascular invasion, poorly differentiated tumors, or sm3 invasion (submucosal invasion to the lower third of the submucosal level).

Surgical Approaches: TAMIS

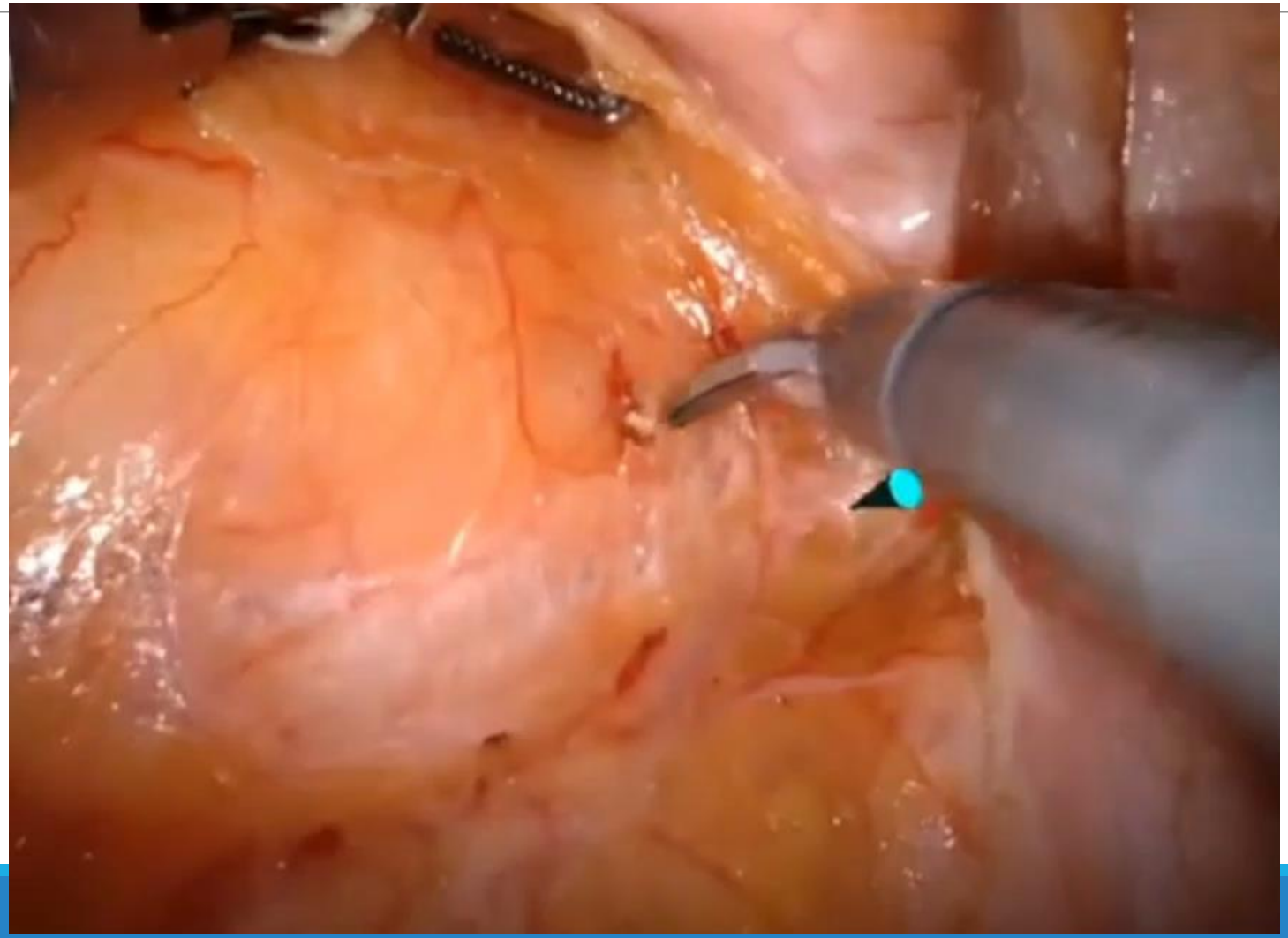


Surgical Approaches: LAR versus APR





Surgical Approaches: The Holy Plane



Role of Radiation Therapy in Rectal Cancer

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Franciscan Health Cancer Center

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Conflicts of Interest

- None

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Work-up

H&P:

- N/V, diarrhea, constipation, stool change, BRBPR, pain, HNPCC, UC (20x ↑ risk)

-Exam:

- Inguinals, abdomen, rectal, female pelvic; fixed/tethered, circumferential involvement, distance from verge, sphincter tone

Labs: CBC, CMP, LFTs, CEA

Imaging:

1. CT C/A/P w oral and IV contrast (PET not indicated per NCCN)
2. MRI pelvis w/ endorectal coil (for T staging; NCCN preferred.
   - Rectal protocol small FOV T2 perpendicular to plane of rectum
   - If no MRI, get EUS- cannot tell CRM or EMVI but better for telling between T1/T2

Procedures

1. Proctoscopy with biopsy
   - MMR /MSI 15% CRC
2. Full colonoscopy to look for synchronous lesions

T Stage

Tis: Lamina propria, muscularia mucosae

T1: submucousa

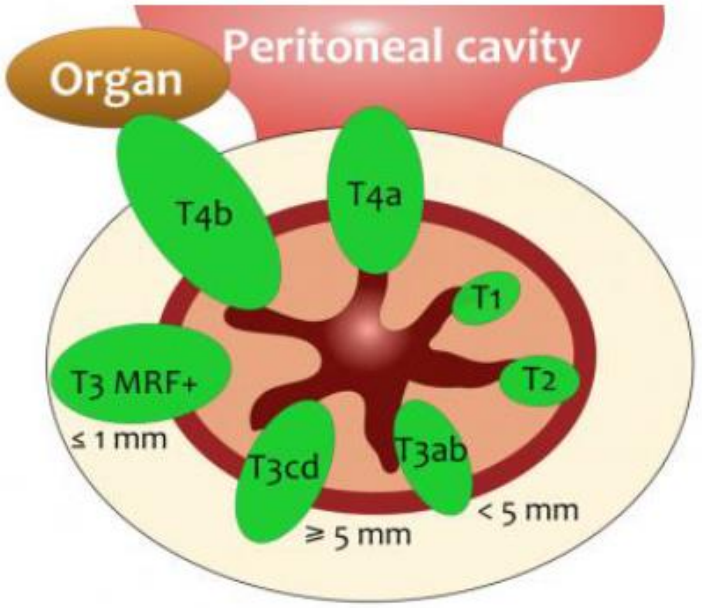
T2: muscularis propria

T3: pericolorectal tissue, through serosa

T4a: Visceral peritoneum

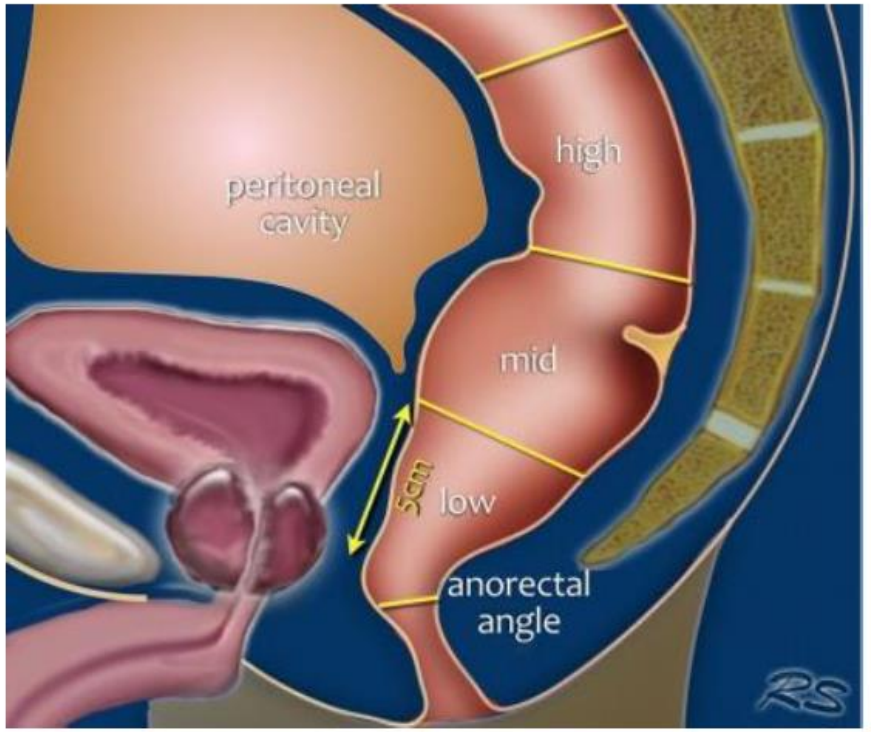
T4b: Adjacent organs

On exam:
T2 = mobile
T3 = tethered
T4 = fixed



Lymph Node Drainage

- Lymph node drainage:
  - Proximal rectum: inferior mesenteric artery → porta hepatis → liver
  - Distal rectum: internal iliac artery → inferior vena cava → lung
  - Anus/sphincter (below dentate line) drains to inguinals ® external iliac
  - Rectum is ~16 cm long and starts at rectosigmoid junction (peritoneal reflection) → dentate line (S3) and ends at anorectal ring
- Upper, middle, lower portions
- Mesorectal fat surrounds to reflxn



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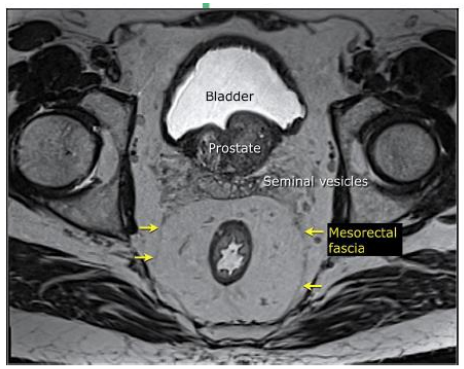
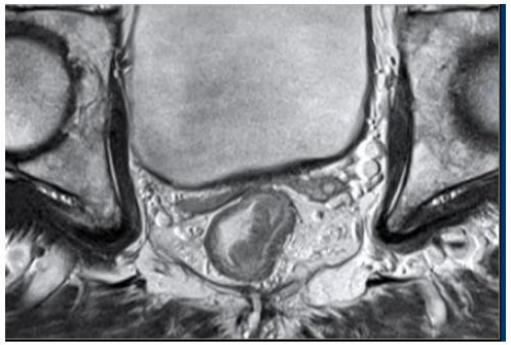
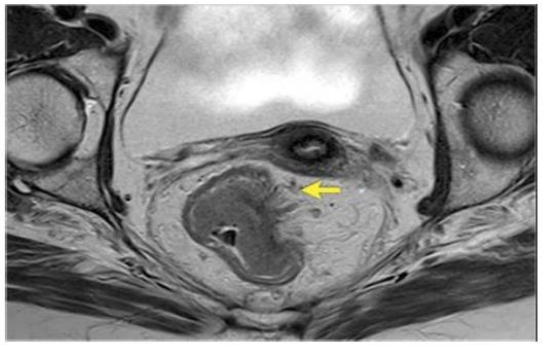
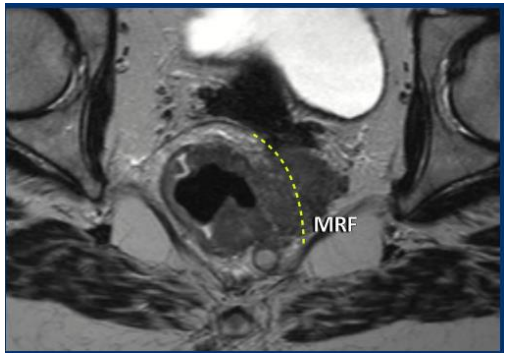
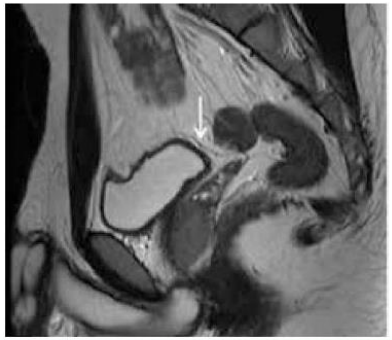
T stage

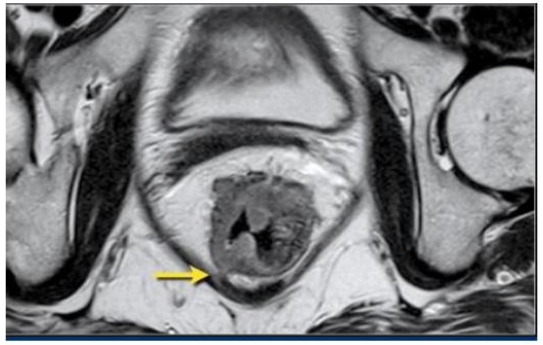


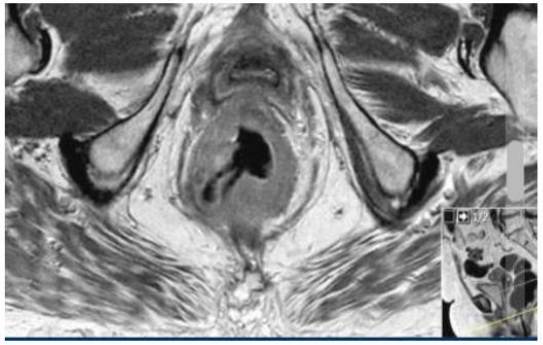


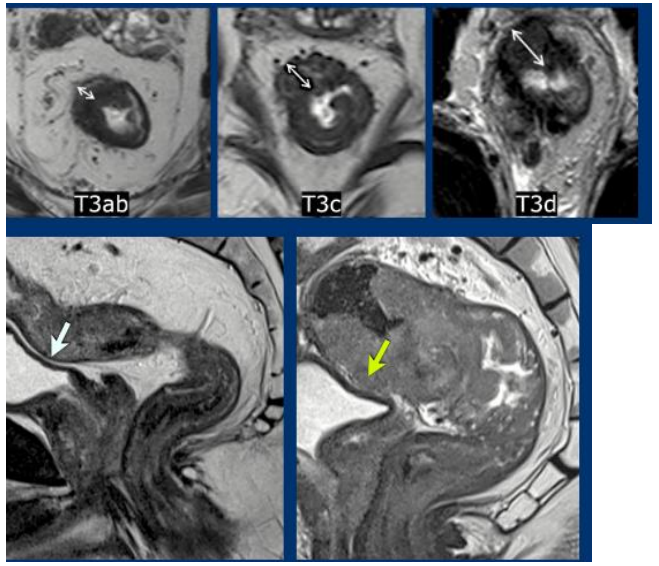












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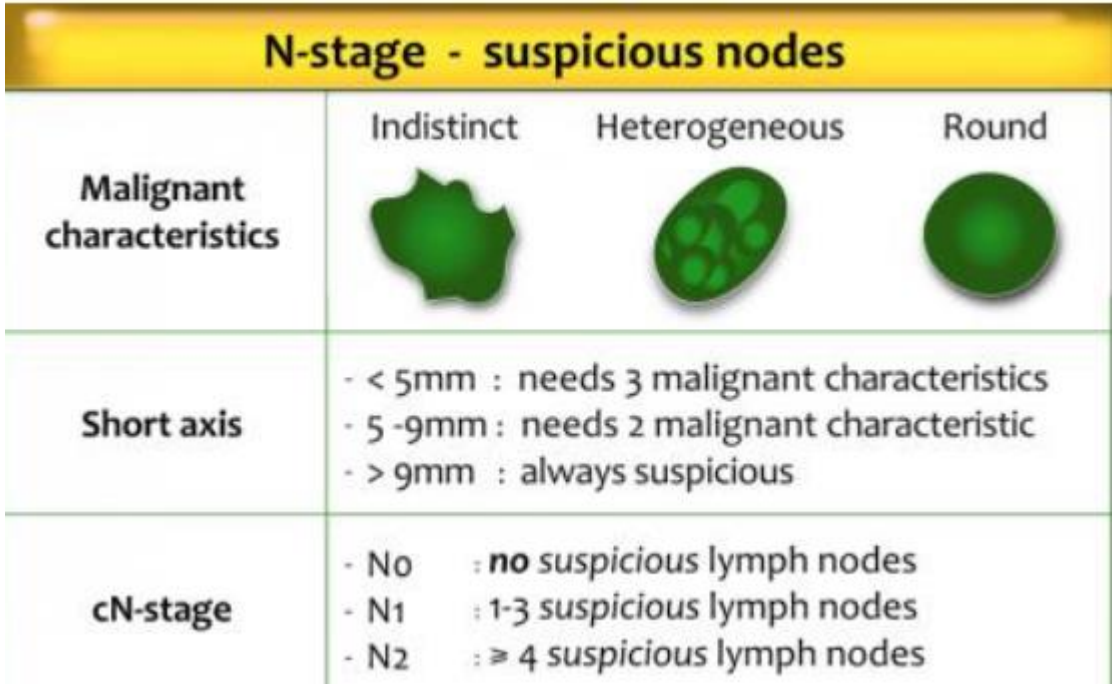
N and M stage

Nodal staging
N1a: 1
N1b: 2-3
N1c: Tumor deposits in subserosa or mesentery w/o regional nodal mets
N2a: 4-6
N2b: 7+

M1a: **1 organ or single non-regional node**
M1b: **> 2 organs** without peritoneal mets
M1c: peritoneal mets



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Overall Stage

Stage I: T1-2 N0
Stage IIA: T3 N0
Stage IIB/C: T4a/T4b N0
Stage IIIA: T1-2N1/N1c or T1N2a
Stage IIIB: T3-4a N1/N1c or T2-3 N2a or T1-2 N2b
Stge IIIC: T4a N2a or T3-4a N2b or T4b N1-2
Stage IVA: M1a
Stage IVB: M1b
Stage IVC: M1c

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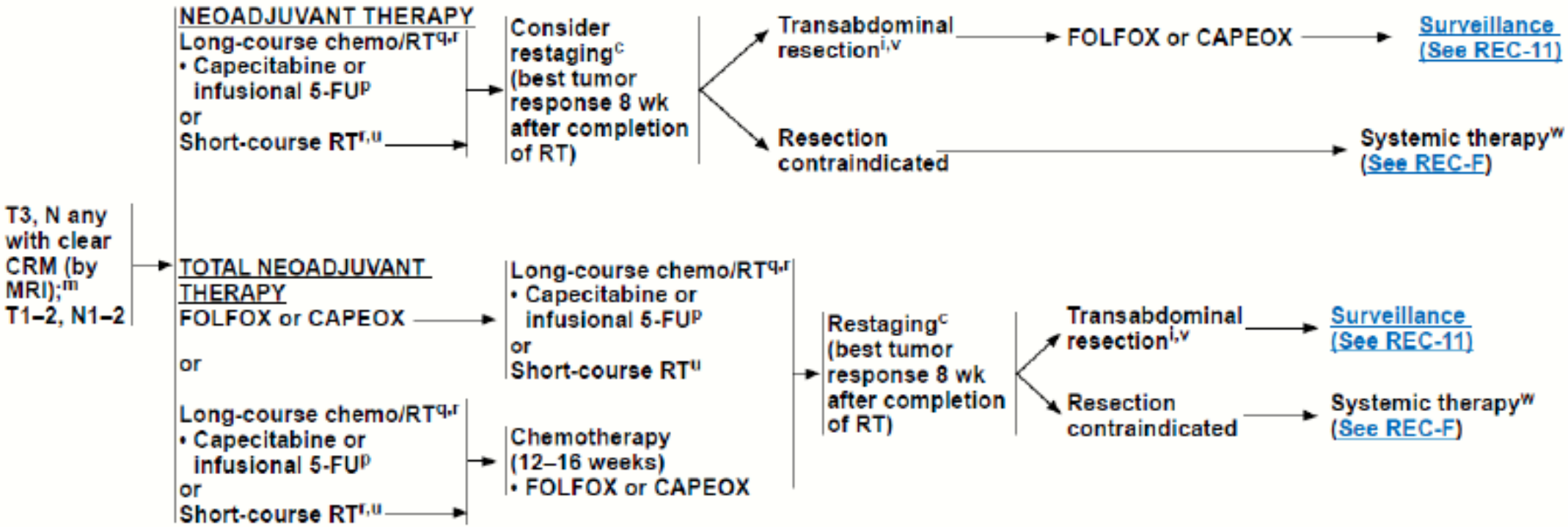
Primary Management Stage 3



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TME

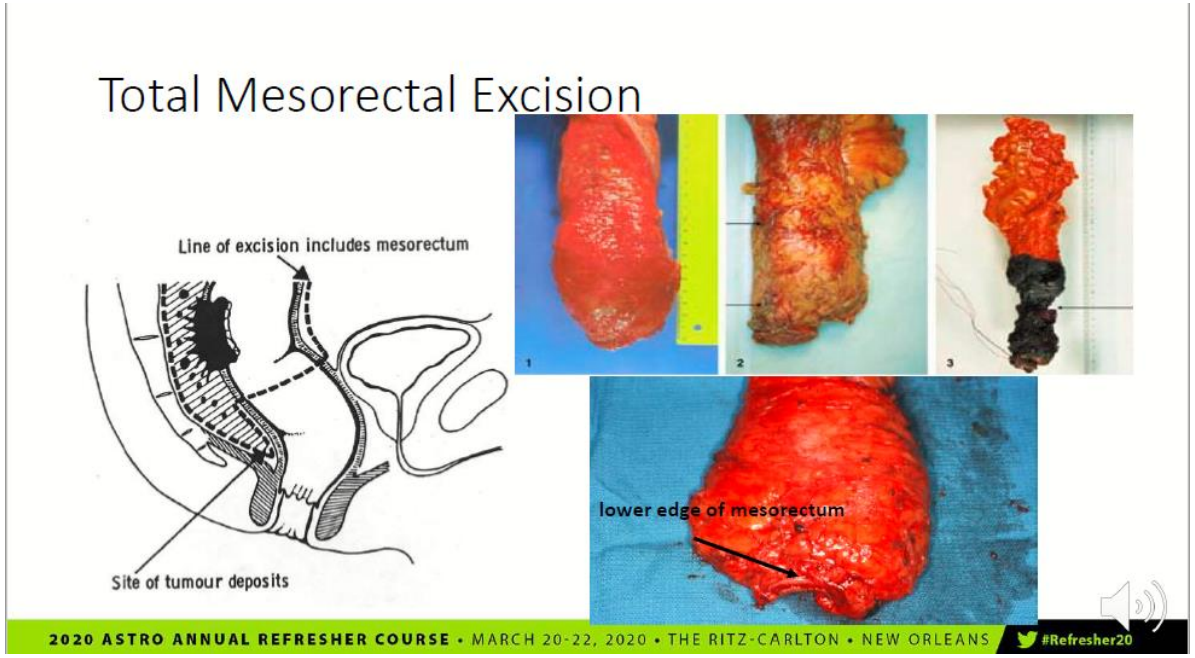
- sharp dissection of entire mesorectum (peri-rectal fat, pre-sacral space), ↓ (+) radial margins
- improved LC (90 vs. 75%). ALL GET TME
- 4-5 cm margin (maybe only be 1-2 cm if low-lying
- How many nodes? 12-14

LAR

- (> 5 cm from verge): mid-upper lesions and spares sphincter

APR:

- 3-5 cm from verge): for low-lying lesions



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Radiation therapy for rectal cancer

Historic Role of RT for Rectal Cancer

- Preop (SC) radiation decreases 10yr LF over TME surgery alone: 11% → 5%

Dutch Trial
Lancet Onc 2011

- Preop (LC) CRT improves 10yr LC over postop: 10.1% → 7.1%.
  - pCR rate w/ 50.4Gy/28 was **8%**

German Rectal Ca Trial
JCO 2012

- **No improvement in DFS or OS.**
  - ***How do we improve DFS?***

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Can we avoid RT in some T3 tumors?

- UK MERCURY: **Straight to surgery**
  - MRI can define "low risk" = T1-T3b with <5mm extramural spread, *any nodal stage*, CRM >1mm, no EMVI.
  - The local control rate for these patients who then underwent good quality TME surgery was 97%

- MSKCC Phase 2 Trial: **Preop chemo alone.**
  - 6 cycles of chemo → restaging. If any response, proceed to surgery.
  - All patients had R0 resection, 25% had pCR.

Evolution of Short-Course RT Trials

- Older trials did surgery w/in 1 week of SCRT
  - Concerns of less downstaging, pCR essentially 0%

Dutch Trial, TROG Trial

- Newer trials waited 4-8wks from SCRT to TME
  - **pCR 11%,** no increased postop complications or toxicity

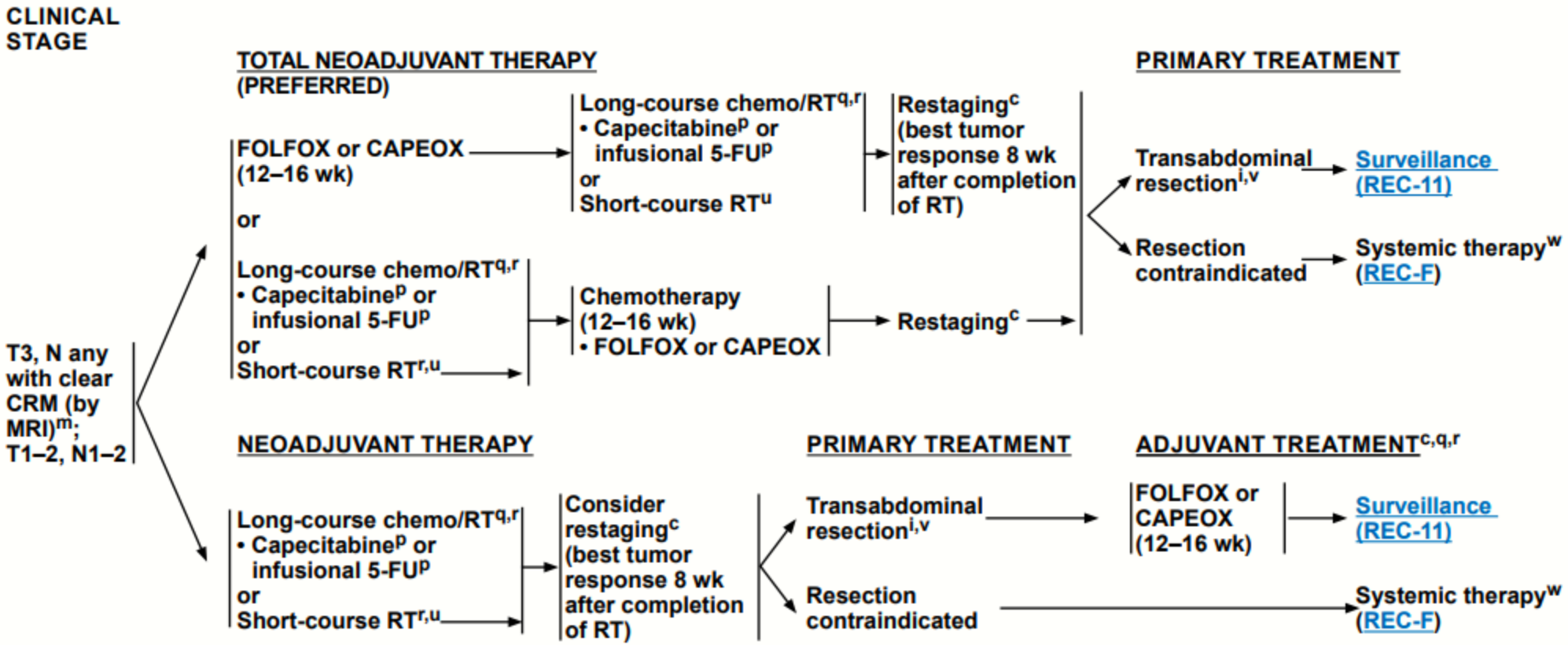
Stockholm III

- Most recent trials gave chemo in the interval btwn SCRT and TME
  - **pCR 28%** on RAPIDO

Polish Trial, RAPIDO

- SCRT is less costly, more convenient.

High Risk Rectal Ca



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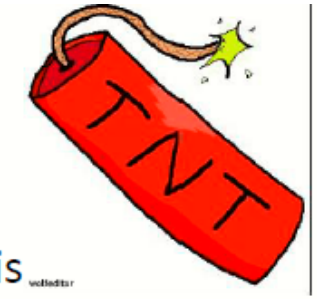
TNT

Rationale for TNT



- With *preop CRT*: LR from >25% → ~5% but distant failure is still 25-30% & is the leading cause of cancer related death.

- **6 months adj chemo historically recommended even after RCT failed to show benefit**
  - Only 40-70% of patients complete adj chemo b/c of toxicity.
  - Moving systemic therapy preop improves tolerability & pCR/downstaging

Brændengen et al
JCO 2008
EORTC 22921

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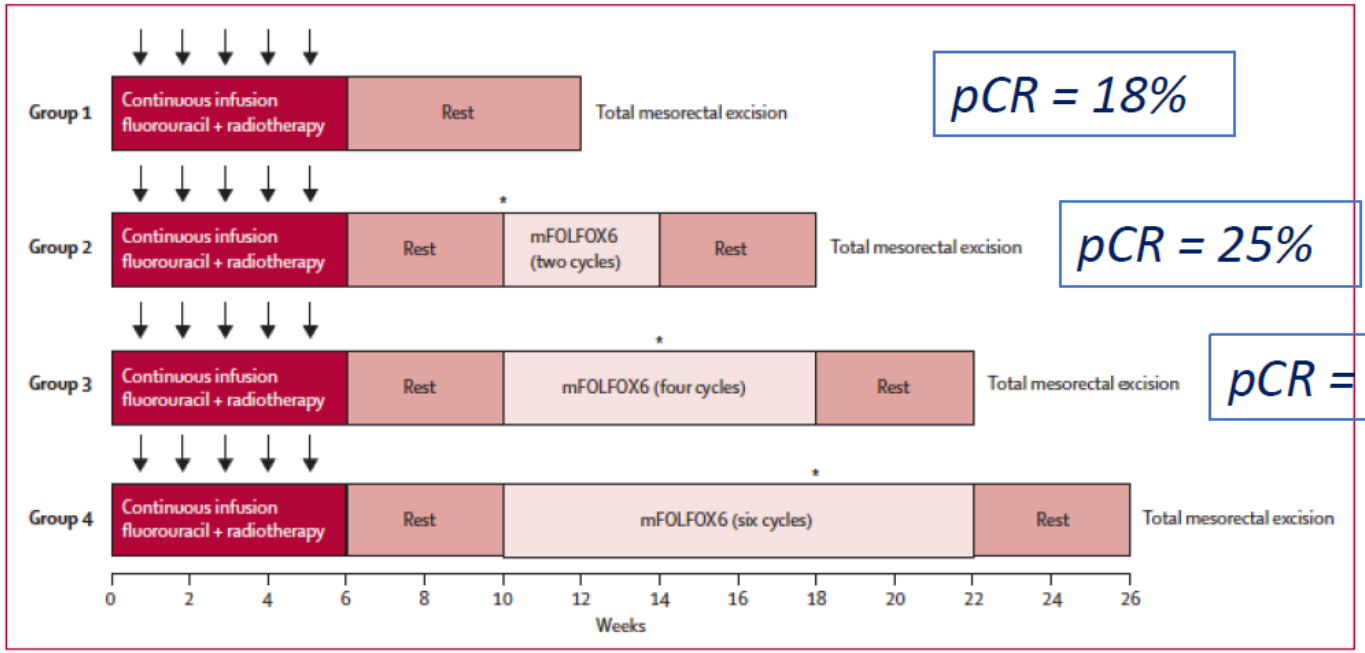
Increased pCR with increasing cycles of FOLFOX

Phase II Data Supporting TNT

- Giving chemo after LC-CRT but before TME improves pCR

Garcia-Aguilar
Lancet Onc 2015



pCR = 18%

pCR = 25%

pCR = 30%

pCR = 38%

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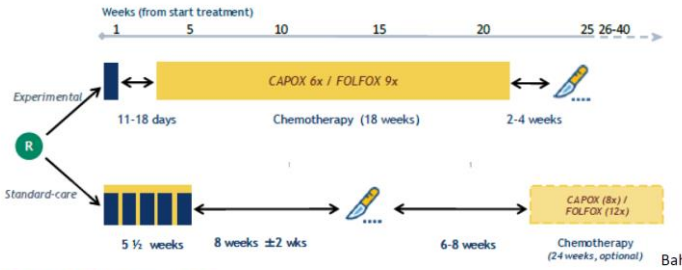
RAPIDO+PRODIGE-23

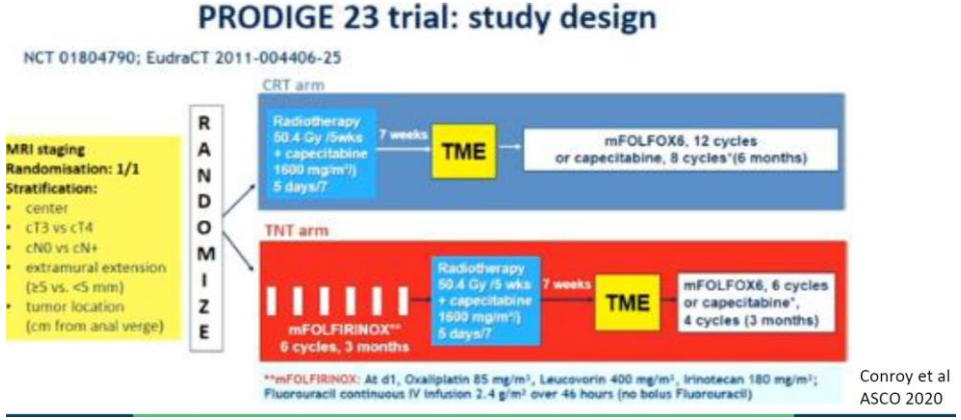
RAPIDO: Study Design

Inclusion criteria: rectal adenoCA w/ >/=1 of the following:
- *T4a/b*
- *EMVI+*
- *N2+*
- *MRF+*
- *Enlarged lateral LNs*



Bahadoer et al

PRODIGE-23



Conroy et al
ASCO 2020

PRODIGE:

DFS better w/ TNT: 75.7% vs 68.5% (HR 0.69; P=.034)

pCR = 27.8% in TNT arm vs 12.1% in CRT arm (p<.001)

RAPIDO:

DR-TF better w/ TNT: 23.7% vs 30.4% (HR 0.75; P=.019)

pCR = 28.4% in TNT arm vs with 14.3% in CRT arm (p<.001)

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OPRA

Organ Preservation in Patients With Rectal Adenocarcinoma Treated With Total Neoadjuvant Therapy

Julio Garcia-Aguilar, MD, PhD[1]; Sujata Patil, PhD[2]; Marc J. Gollub, MD[3]; Jin K. Kim, MD[1]; Jonathan B. Yuval, MD[1]; Hannah M. Thompson, MD[1]; Floris S. Verheij, MD[1]; Dana M. Omer, MD[1]; Meghan Lee, BS[1]; Richard F. Dunne, MD[4]; Jorge Marcet, MD[5]; Peter Cataldo, MD[6]; Blase Polite, MD[7]; Daniel O. Herzig, MD[8]; David Liska, MD[9]; Samuel Oommen, MD[10]; Charles M. Friel, MD[11]; Charles Ternent, MD[12]; Andrew L. Coveler, MD[13]; Steven Hunt, MD[14]; Anita Gregory, MD[15]; Madhulika G. Varma, MD[16]; Brian L. Bello, MD[17]; Joseph C. Carmichael, MD[18]; John Krauss, MD[19]; Ana Gleisner, MD[20]; Philip B. Paty, MD[1]; Martin R. Weiser, MD[1]; Garrett M. Nash, MD[1]; Emmanouil Pappou, MD[1]; José G. Guillem, MD[21]; Larissa Temple, MD[22]; Iris H. Wei, MD[1]; Maria Widmar, MD[1]; Sabrina Lin, MS[2]; Neil H. Segal, MD, PhD[23]; Andrea Cercek, MD[23]; Rona Yaeger, MD[23]; J. Joshua Smith, MD, PhD[1]; Karyn A. Goodman, MD[24]; Abraham J. Wu, MD[25]; and Leonard B. Saltz, MD[23]

PURPOSE Prospective data on the efficacy of a watch-and-wait strategy to achieve organ preservation in patients with locally advanced rectal cancer treated with total neoadjuvant therapy are limited.

METHODS In this prospective, randomized phase II trial, we assessed the outcomes of 324 patients with stage II or III rectal adenocarcinoma treated with induction chemotherapy followed by chemoradiotherapy (INCT-CRT) or chemoradiotherapy followed by consolidation chemotherapy (CRT-CNCT) and either total mesorectal excision (TME) or watch-and-wait on the basis of tumor response. Patients in both groups received 4 months of infusional fluorouracil-leucovorin-oxaliplatin or capecitabine-oxaliplatin and 5,000 to 5,600 cGy of radiation combined with either continuous infusion fluorouracil or capecitabine during radiotherapy. The trial was designed as two stand-alone studies with disease-free survival (DFS) as the primary end point for both groups, with a comparison to a null hypothesis on the basis of historical data. The secondary end point was TME-free survival.

RESULTS Median follow-up was 3 years. Three-year DFS was 76% (95% CI, 69 to 84) for the INCT-CRT group and 76% (95% CI, 69 to 83) for the CRT-CNCT group, in line with the 3-year DFS rate (75%) observed historically. Three-year TME-free survival was 41% (95% CI, 33 to 50) in the INCT-CRT group and 53% (95% CI, 45 to 62) in the CRT-CNCT group. No differences were found between groups in local recurrence-free survival, distant metastasis-free survival, or overall survival. Patients who underwent TME after restaging and patients who underwent TME after regrowth had similar DFS rates.

CONCLUSION Organ preservation is achievable in half of the patients with rectal cancer treated with total neoadjuvant therapy, without an apparent detriment in survival, compared with historical controls treated with chemoradiotherapy, TME, and postoperative chemotherapy.

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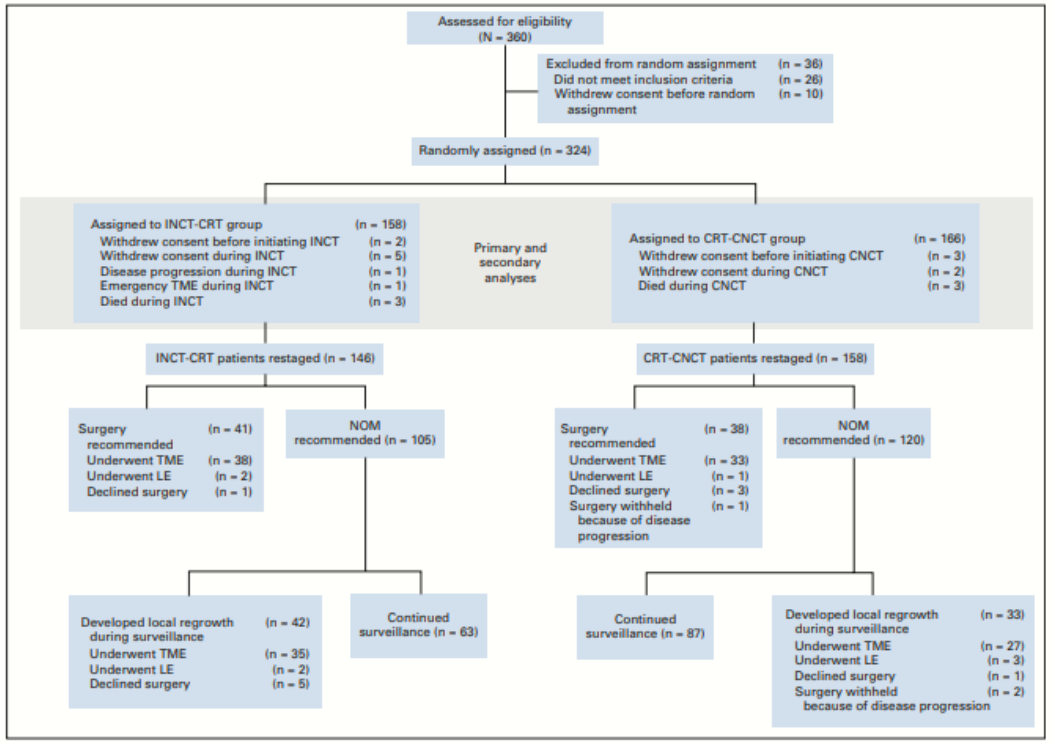

FIG 1. CONSORT diagram illustrating the eligibility, random assignment, outcomes, and follow-up of the trial cohort. Primary and secondary analyses of the 158 INCT-CRT and 166 CRT-CNCT patients followed an intention-to-treat principle. CRT-CNCT, chemoradiotherapy followed by consolidation chemotherapy; INCT-CRT, induction chemotherapy followed by chemoradiotherapy; LE, local excision; NOM, nonoperative management; TME, total mesorectal excision.

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TABLE 1. Baseline Demographics and Clinical Characteristics of the Full Cohort

Characteristic	INCT-CRT Group (n = 158)	CRT-CNCT Group (n = 166)
Median age, year (IQR)	59 (51-68)	56 (49-67)
Female, No. (%)	55 (35)	64 (39)
Race, No. (%)		
White	130 (82.3)	143 (86.1)
Black	10 (6.3)	8 (4.8)
Asian	10 (6.3)	7 (4.2)
Other	3 (1.9)	1 (0.6)
Unknown	5 (3.2)	7 (4.2)
Ethnicity, No. (%)		
Hispanic or Latino	7 (4)	11 (7)
Non-Hispanic	151 (96)	154 (93)
Unknown	0 (0)	1 (0.06)
cT classification, No. (%)		
cT1-2	11 (7)	21 (13)
cT3	124 (78)	126 (76)
cT4	23 (15)	19 (11)
cN classification, No. (%)		
cN-negative	47 (30)	47 (28)
cN-positive	111 (70)	119 (72)
Median tumor distance from anal verge, cm (IQR)	4.3 (3.0-6.3)	4.5 (3.0-6.5)
High-grade tumor, No. (%)	7 (4)	8 (5)

NOTE. Percentages may not total 100 because of rounding. There were no significant differences between the two groups with respect to the baseline patient characteristics.

Abbreviations: cN, clinical nodal classification; CRT-CNCT, chemoradiotherapy followed by consolidation chemotherapy; cT, clinical tumor classification; INCT-CRT, induction chemotherapy followed by chemoradiotherapy; IQR, interquartile range.

TABLE 2. Total Neoadjuvant Therapy Results for the Full Cohort

Characteristic	INCT-CRT Group (n = 158)	CRT-CNCT Group (n = 166)
Started systemic chemotherapy, No. (%)	156 (99)	156 (94)
Received FOLFOX	117 (74)	116 (70)
Received eight cycles of FOLFOX[a]	101/117 (86)	97/116 (84)
Received CAPEOX	33 (21)	34 (20)
Received five cycles of CAPEOX[a]	28/33 (85)	30/34 (88)
Received FOLFOX and CAPEOX	6 (4)	6 (4)
Started radiotherapy, No. (%)	147 (93)	163 (98)
Received concurrent FU or capecitabine	144 (98)	163 (100)
No concurrent chemotherapy	3 (2)	0 (0)
Median radiation dose, cGy (IQR)	5,400 (5,040-5,400)	5,400 (5,040-5,600)
Median time from treatment initiation to restaging (IQR), weeks	34.9 (32.6-36.5)	34.0 (32.0-37.0)
Median time from treatment completion to restaging (IQR), weeks	8.0 (6.5-9.4)	7.7 (5.1-9.4)
Median time from completion of chemoradiation to restaging (IQR), weeks	8.0 (6.5-9.4)	28.5 (26.4-31.4)
Adverse events (grade 3+) during TNT, No. (%)[b]	64 (41)	57 (34)
Grade 3	54 (34)	52 (31)
Grade 4	17 (11)	11 (7)
Grade 5	2 (1)	3 (2)

NOTE. Percentages may not total 100 because of rounding.

Abbreviations: CAPEOX, capecitabine and oxaliplatin; cGy, centigray; CRT-CNCT, chemoradiotherapy followed by consolidation chemotherapy; FOLFOX, infusional fluorouracil, leucovorin, and oxaliplatin; FU, fluorouracil; INCT-CRT, induction chemotherapy followed by chemoradiotherapy; IQR, interquartile range; TNT, total neoadjuvant therapy.

[a]Patients who completed the intended cycles of both fluoropyrimidine-based chemotherapy as well as oxaliplatin. 8+ cycles of FOLFOX or 5+ cycles of CAPEOX. Patients who received a mix of FOLFOX and CAPEOX were not considered to have completed the intended treatment course.

[b]Highest grade of adverse event per patient is reported.

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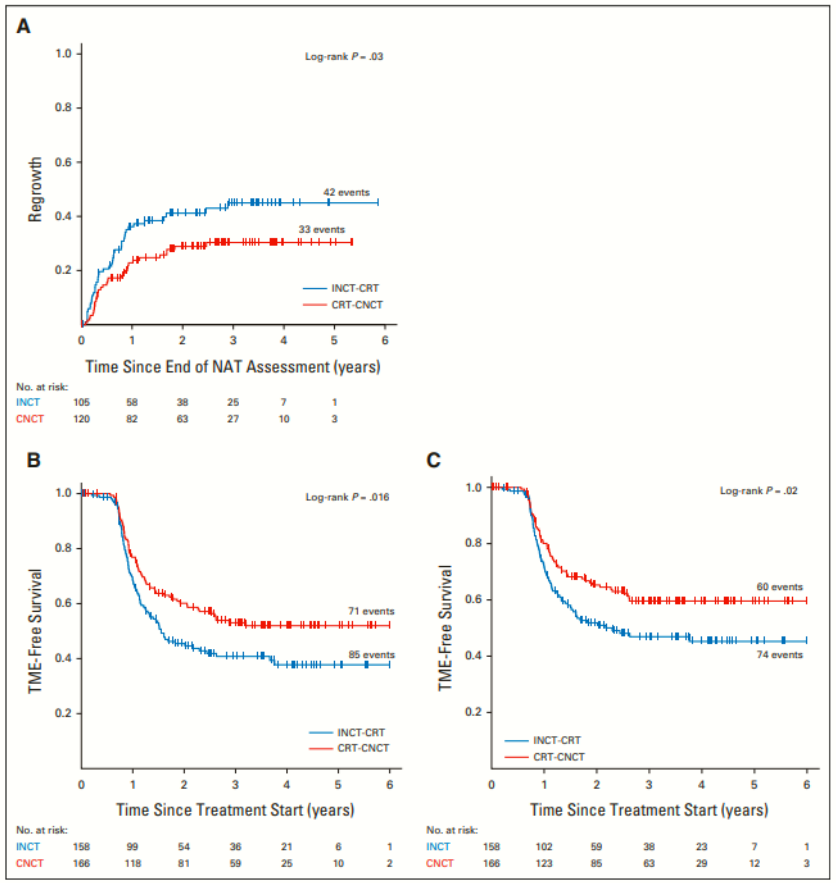

FIG 3. Kaplan-Meier estimates of (A) time to regrowth in watch-and-wait patients, (B) TME-free survival by intention to treat, and (C) for patients who underwent TME. CRT-CNCT, chemoradiotherapy followed by consolidation chemotherapy; INCT-CRT, induction chemotherapy followed by chemoradiotherapy; NAT, neoadjuvant therapy; TME, total mesorectal excision.

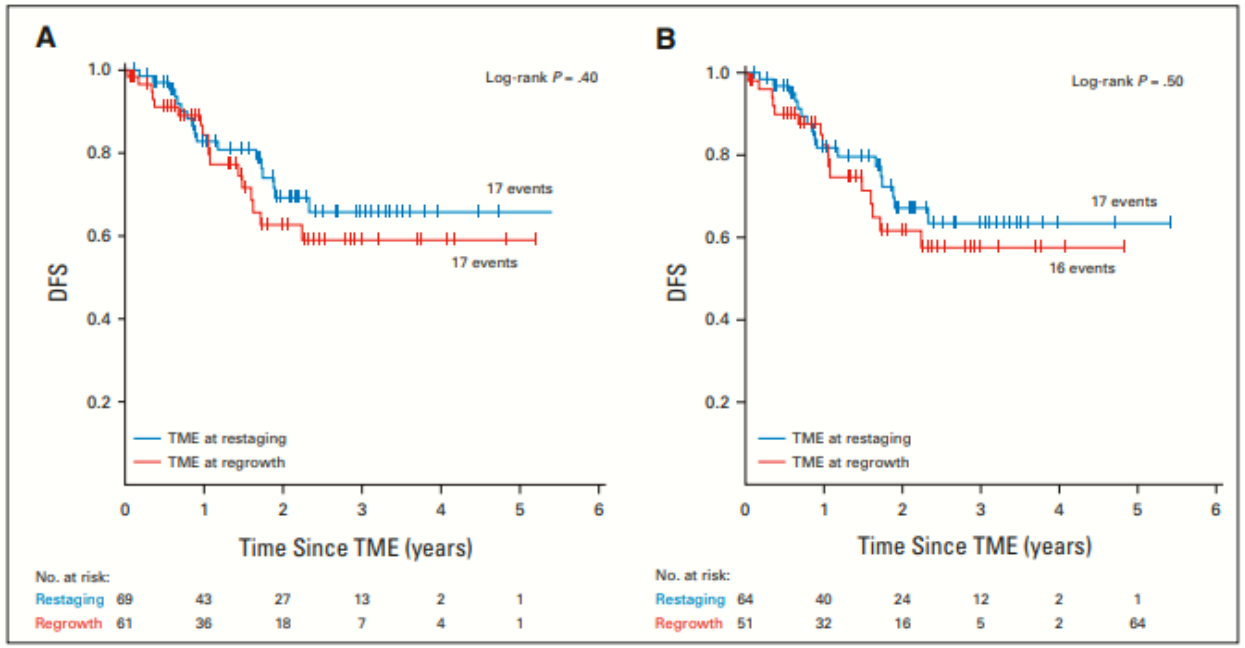

FIG 4. Kaplan-Meier estimates of DFS for (A) patients recommended TME after restaging and after tumor regrowth by intention to treat and (B) patients who actually underwent TME. Patients who developed distant metastasis before TME was recommended (three at restaging and six at regrowth) and patients in whom TME was not performed because of disease progression found at surgery (one at restaging and two at regrowth) are not included in the analysis. Six patients in each group have not reached the first follow-up clinical assessment after TME. DFS, disease-free survival; TME, total mesorectal excision.

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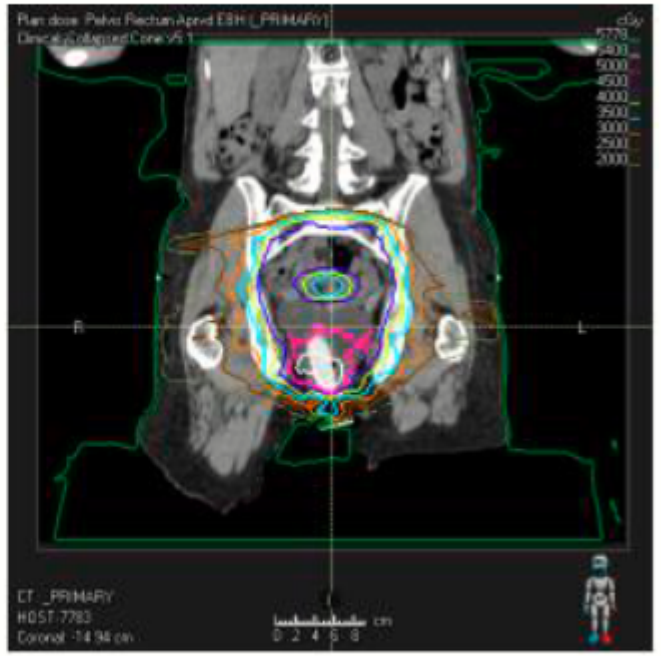
Non-operative management continued

- Dose/Fractionation: 54Gy in 27 fractions
  - 45Gy in 25 fraction pelvis w/ SIB 50Gy in 25 to tumor + margin
  - Sequential 4Gy boost to the tumor + margin to total 54Gy
- Volumes: Standard elective pelvis (Myerson et al RTOG atlas)
  - Internal iliacs, perirectal, presacral, obturator
  - **elective inguinal coverage is controversial for low rectal tumors**
- 3D vs IMRT/VMAT depending on ability to meet constaints. (I use VMAT when I go to 54Gy)
- Chemo can begin ~2 weeks after chemoradiation



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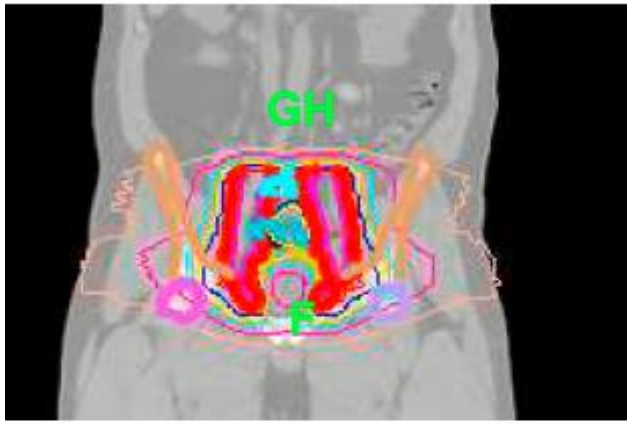

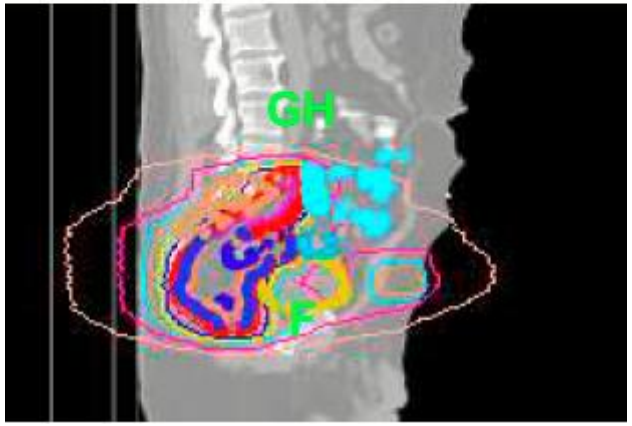

- CT simulation with IV and oral contrast
- Prone, arms up, belly board, wire scars (for APR), marker at anal verge, vaginal marker for female, full bladder.
- CT from L1 to mid femur
-
- Daily CBCT for bladder filling
- CTV_45 Gy: all gross disease, entire mesorectum, presacral, internal iliac nodes (**external lilacs also if T4, anal canal**)
- CTV_50.4: GTV (or pre-op tumor) + **3 cm + presacral nodes and mesorectum/sacral hollow→**

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Acute toxicity of RT

- Diarrhea
- Acute proctitis
- Thrombocytopenia
- Leukopenia
- Dysuria
- 5FU toxicity
  - Cardiac toxicity including CP, MI, A fib, myocarditis
  - Vasospasm STE
    - 12 hrs after initiation to 1-2 d
  - Mechanism.
    - Altered DPD enzyme activity--> toxic fluroacetate--> ischmemia/Takasubo--> vasospasm
  - Prevention
    - Infusion rather than bolus
    - Imdur +CCB --> 12 min push with cardiologist present
    - 12 hrs after repeat this
    - Penn Case series: 100% got through treatment (N <20)

Late Toxicity:

- Peristent diarrhea, proctitis, frequent BMs
- Anastamotic Strictures
- SBO
- Incontinence
- Impotence/Sterility
- Vaginal dilators for females!
- Swedish 5x5 major complication was SBO, but also:
    1) Bowel frequency
    2) Fecal incontinence
    3) Impaired social life

Thank you!

- Questions?

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Treatment of Non metastatic rectal cancer- Medical Oncology perspective

Dr. Nibal Saad

Oncology & Hematology Specialists

Franciscan Physician Network

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Colon vs rectal cancer

- Although pathology of rectal cancer is similar to colon cancer, the anatomic location of rectum made local recurrence big challenge.
- That makes multidisciplinary approach very important to decrease local recurrence rate and improve cancer control
- Staging:
  - MRI pelvis vs EUS
  - CT CAP
  - No PET scan

Surgery

- Surgery alone is appropriate for T1 disease, otherwise chemotherapy and radiation therapy are needed
- With multidisciplinary approach, 5 yrs local recurrence rate dropped to 5-10%
- Preferred surgery is TME

- To improve over surgery alone, two approaches were used
  - PreOperative Short course RT 5 Gyx 5 days (compared with surgery alone, Swedish trial: local recurrence 11 vs 27%, 5yrs-OS 58 vs 48%, another Dutch trial showed improved local recurrence but not OS), or
  - PreOperarive Concurrent Chemo radiation with 50.4 Gy (45+ 5.4 Gy local boost) over 5-6 weeks with radio sensitizing chemotherapy
- Both approaches decreased loco regional failure
- For sphincter preserving surgery however, only prolonged CRT approach showed enough tumor shrinkage
- Prolonged CRT approach is the preferred one in USA

History of multimodality approach

- Surgery < surgery + RT (short course or long course): combination therapy won
  - (Swedish trial:
    - local recurrence 11 vs 27%,
    - 5yrs-OS 58 vs 48%
    - N Engl J Med 1997; 336:980-987
  - another Dutch trial showed improved local recurrence but not OS),

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- Surgery+ adj RT < Surgery+ adj CRT (5FU based chemo): tri modality won
  - local recurrence 25 vs 13%, distant mets 46 vs 29%,
  - Krook et al NEJM 1991

- Surgery + CRT (5FU bolus) < surgery + CRT (5FU continuous)
- relapse 53 vs 63%, OS 60 vs 70%
- O'Connell et al NEGM 1994

- Surgery + adj CRT continuous 5FU = Surgery + adj CRT Capcitabine.
  - (3 yrs DFS 67vs 75%, 5yr OS 67 VS76%)
  - Hofleinz et al Lancet oncol 2012
  - Currently either cont 5FU or Capecitabine with RT are acceptable standard of care

- surgery + adj CRT < neoadj CRT+ surgery
  - Local recurrence 13 vs 6%, OS 74vs76 %, G3-4 tox 40 vs 27% .
  - Sauer et al NEJM 2004
  - Pt who gets upfront surgery for presumed T1 disease but ends up with more advanced disease should get adj CRT

- Neoadj CRT + surgery vs Neoadj CRT (oxaliplatin based),
- oxaliplatin was associated with more toxicity

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- Adjuvant chemotherapy after neoadjuvant CRT and surgery
  - Meta analysis did not show benefit of adjuvant chemo. That was done on old chemo regimens however
  - ADORE trial, 2019, a phase III Korean trial on patient who received neoadjuvant CRT and had postoperative stage II and III. Compared adj 5fU vs FOLFOX. 6 yr DFS 68% vs 57%
  - NCCN still recommend adj chemotherapy even in cPR patients

TNT

- CAPOX+RT then Surgery then CAPOX x4 vs TNT (CAPOX x4 ->CAPOX+RT -> surgery.
  - cPR same, G3 tox was less in TNT 19 vs54%

VOLUME 28 · NUMBER 5 · FEBRUARY 10 2010

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Phase II, Randomized Study of Concomitant Chemoradiotherapy Followed by Surgery and Adjuvant Capecitabine Plus Oxaliplatin (CAPOX) Compared With Induction CAPOX Followed by Concomitant Chemoradiotherapy and Surgery in Magnetic Resonance Imaging–Defined, Locally Advanced Rectal Cancer: Grupo Cáncer de Recto 3 Study

Carlos Fernández-Martos, Carles Pericay, Jorge Aparicio, Antonieta Salud, MariaJose Safont, Bertomeu Massuti, Ruth Vera, Pilar Escudero, Joan Maurel, Eugenio Marcuello, Jose Luis Mengual, Eugenio Saigi, Rafael Estevan, Moises Mira, Sonia Polo, Ana Hernandez, Manuel Gallen, Fernando Arias, Javier Serra, and Vicente Alonso

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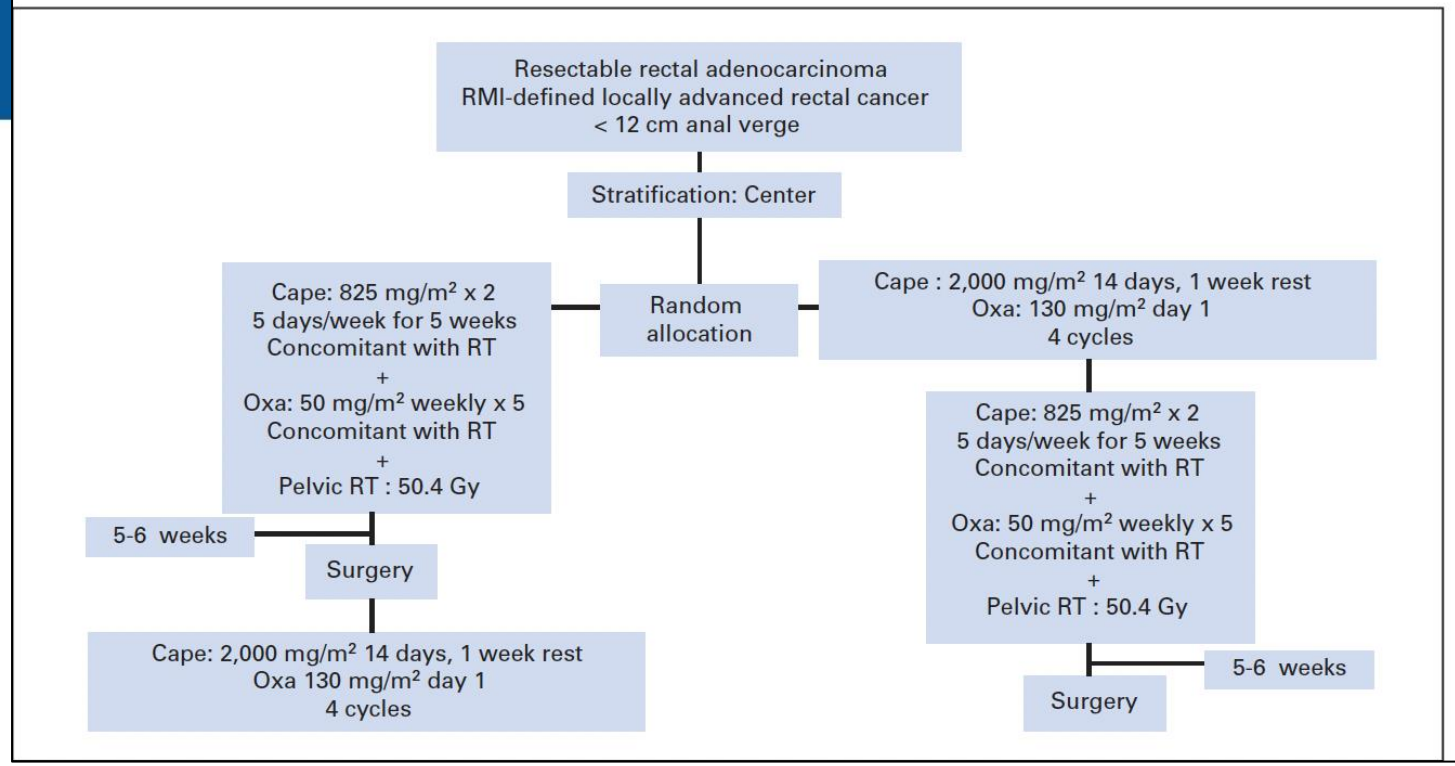

Fig 2. Schema for randomized, Grupo Cáncer de Recto 3, phase II study. Cape, capecitabine; RT, radiation therapy; Oxa, oxaliplatin.

Adjuvant or Induction Chemotherapy in Rectal Cancer

Table 4. Toxicity, Surgical Complications, and Compliance

Variable	Arm A: Postoperative Adjuvant CT (n = 52)			Arm B: Induction CT (n = 56)			*P*
	No.	Total No.	%	No.	Total No.	%	
Any grades 3 to 4 toxicity during CT/RT	15	49	29	12	53	23	.360
Any grades 3 to 4 toxicity during adjuvant/induction*	20	37	54	10	54	19	.0004

- CRT + 0, 2, 4, 6 cycles of FOLFOX
  - TNT improved cPR compared with no neoadj chemo 38 vs 18%

Effect of adding mFOLFOX6 after neoadjuvant chemoradiation in locally advanced rectal cancer: a multicentre, phase 2 trial

Prof Julio Garcia-Aguilar, MD • Oliver S Chow, MD • Prof David D Smith, PhD • Prof Jorge E Marcet, MD • Prof Peter A Cataldo, MD • Prof Madhulika G Varma, MD • et al. Show all authors

Published: July 14, 2015 • DOI: https://doi.org/10.1016/S1470-2045(15)00004-2 • Check for updates

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TNT

- CAO/ARP/AIO-12 phase II trial : TNT with consolidative chemo (FOLFOX) vs TNT with induction chemo
  - Better cPR in consolidation chemo 25 vs 17%

original reports

Randomized Phase II Trial of Chemoradiotherapy Plus Induction or Consolidation Chemotherapy as Total Neoadjuvant Therapy for Locally Advanced Rectal Cancer: CAO/ARO/AIO-12

Emmanouil Fokas, MD, DPhil[1,2,3,4]; Michael Allgäuer, MD[5]; Bülent Polat, MD[6]; Gunther Klautke, MD[7]; Gerhard G. Grabenbauer, MD[8]; Rainer Fietkau, MD[9]; Thomas Kuhnt, MD[10]; Ludger Staib, MD[11]; Thomas Brunner, MD[12,13]; Anca-Ligia Grosu, MD[12]; Wolff Schmiegel, PhD, MD[14]; Lutz Jacobasch, MD[15]; Jürgen Weitz, MD[2,16,17]; Gunnar Folprecht, MD[2,16,17]; Anke Schlenska-Lange, MD[2]; Michael Flentje, MD[6]; Christoph-Thomas Germer, PhD[6]; Robert Grützmann, MD[9]; Matthias Schwarzbach, MD[18]; Vittorio Paolucci, MD[19]; Wolf O. Bechstein, MD[1]; Tim Friede, PhD[20]; Michael Ghadimi, MD[20]; Ralf-Dieter Hofheinz, MD[21]; and Claus Rödel, MD[1,2,3,4]; on behalf of the German Rectal Cancer Study Group

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- OPRA trial : TNT with consolidative chemo vs TNT with induction chemo
  - 3 yr total mesorectal free survival 41% (induction chemo)vs 53% in the consolidation group
  - 3yr DFS similar

Meeting Abstract | 2020 ASCO Annual Meeting I

GASTROINTESTINAL CANCER—COLORECTAL AND ANAL

Preliminary results of the organ preservation of rectal adenocarcinoma (OPRA) trial.

Julio Garcia-Aguilar, Sujata Patil, Jin K. Kim, Jonathan B. Yuval, Hannah Thompson, Floris Verheij, Meghan Lee, Leonard B. Saltz, on behalf of the OPRA Consortium

Colorectal Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY; Department of Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY; , Memorial Sloan Kettering Cancer Center, New York, Memorial Sloan Kettering Cancer Center, New York, NY

3-year rates with 95% CI.

	Induction		Consolidation		p*
DFS	78%	(70%,87%)	77%	(69%,86%)	0.90
DMFS	81%	(74%,90%)	83%	(76%,91%)	0.86
OP	43%	(35%,54%)	58%	(49%,69%)	0.01

*log-rank test

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- RAPIDO trial:
  - Short course RT then chemo then surgery vs CRT->Sx->chemo
  - TNT showed better cPR 28 vs14%, better 3 yrs distant met free survival 27 vs 20%, OS same

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- PRODIGE 23 trial: CRT->FOLFIRINOX x3m ->TME-> FOLFOX x3 m vs standard approach
  - cPR 27 vs11.7% improved DFS, Met FS,
  - OS is not mature

ARTICLES | VOLUME 22, ISSUE 5, P702-715, MAY 2021 Download Full Issue

Neoadjuvant chemotherapy with FOLFIRINOX and preoperative chemoradiotherapy for patients with locally advanced rectal cancer (UNICANCER-PRODIGE 23): a multicentre, randomised, open-label, phase 3 trial

Prof Thierry Conroy, MD • Prof Jean-François Bosset, MD • Pierre-Luc Etienne, MD • Emmanuel Rio, MD • Éric François, MD • Nathalie Mesgouez-Nebout, MD • et al. Show all authors • Show footnotes

Published: April 13, 2021 • DOI: https://doi.org/10.1016/S1470-2045(21)00079-6 • Check for updates

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Omit surgery !

- Meta analysis of 23 studies: 867 pts, with patient who has clinical complete remission
  - Local regrowth rate in non operative group 15-25%
  - Most of them can be successfully treated with salvage therapy
- Non operative approach is still not standard of care, and it should be done only in centers with experienced multidisciplinary team

Omit radiation ?

- FOWARC trial: phase III trial in China,
  - Neoadj FOLFOX vs CRT
  - Similar rate of local recurrence , 3 yr DFS, 3 yr OS

- PROSPECT trial: 2023 ASCO standard of care vs FOLFOX with selective use of CRT
  - Include: cT2N+, cT3
  - Exclude: T4, distal tumor, threatened CRM, > 4 LN
  - Intervention group: FOLFOX x6 -> restage.
    - If regression >20% proceed with TME
    - If regression < 20% proceed with CRT then TME
  - Results: 9% of the intervention arm needed CRT
  - 5yr DFS 78 % vs 80 meeting non inferiority cutoff

LBA2 **Plenary Session**

PROSPECT: A randomized phase III trial of neoadjuvant chemoradiation versus neoadjuvant FOLFOX chemotherapy with selective use of chemoradiation, followed by total mesorectal excision (TME) for treatment of locally advanced rectal cancer (LARC) (Alliance N1048).

Outcomes	5FUCRT	FOLFOX with selective 5FUCRT	Hypothesis testing	HR (CI)*	P&
N treated per protocol	543	585			
5-yr DFS, %	78.6 (75.4-81.8)	80.8 (77.9-83.7)	Non-Inferiority	.92 (.74-1.14)	.0051
5-yr Local Recurrence Free Survival, %	98.4 (97.3-99.6)	98.2 (97.1-99.4)	Superiority	1.18 (.44-3.16)	.74
5-yr OS, %	90.2 (87.6-92.9)	89.5 (87.0-92.2)	Superiority	1.04 (.74-1.44)	.84
#R0 resection %	97.1	98.9	Superiority		.094
#Pathologic CR, %	24.3	21.9	Superiority		.35

*Two-sided 90.2% CI for DFS and two-sided 95% CI for 2° endpoints. &One-sided NI testing for DFS and two-sided superiority testing for 2° endpoints. #Among patients who had TME.

Immunotherapy

- 5% of rectal cancer are MSI-H
- Single institution phase II study. Dostarlimab /PDL1i was used in 12 pts with locally advanced rectal ca with MSI-H
- 100% clinical complete response with median fu 12 months

- Omit RT and surgery ? !

RESEARCH SUMMARY

PD-1 Blockade in Mismatch Repair–Deficient, Locally Advanced Rectal Cancer

Cercek A et al. DOI: 10.1056/NEJMoa2201445

CLINICAL PROBLEM

Standard treatment for locally advanced rectal cancer includes neoadjuvant chemotherapy and radiation, followed by surgical resection of the rectum. This approach, however, is associated with substantial complications and toxic effects. Research suggests that immune checkpoint blockade alone is highly effective in patients with mismatch repair–deficient metastatic colorectal cancer; whether this strategy is effective in mismatch repair–deficient, locally advanced rectal cancer is unknown.

CLINICAL TRIAL

Design: A prospective, phase 2, single-group study examined the efficacy and safety of neoadjuvant therapy with the programmed death 1 (PD-1) inhibitor dostarlimab in patients with mismatch repair–deficient stage II or III rectal adenocarcinoma.

Intervention: Adult patients received intravenous dostarlimab every 3 weeks for 6 months, to be followed by chemoradiotherapy and total mesorectal excision. Patients with a clinical complete response to dostarlimab could forgo chemoradiotherapy and surgery. A key primary end point was overall response to dostarlimab alone or to dostarlimab plus chemoradiotherapy, determined on the basis of rectal magnetic resonance imaging, endoscopic visualization, and digital rectal examination.

RESULTS

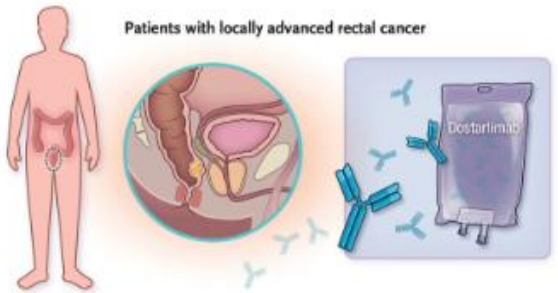
Efficacy: 12 of 16 enrolled patients have already completed 6 months of dostarlimab. All 12 had a clinical complete response, with no evidence of tumor on any diagnostic test. During a median follow-up of 12 months, no patient received chemoradiotherapy or underwent surgery, and none had disease progression or recurrence.

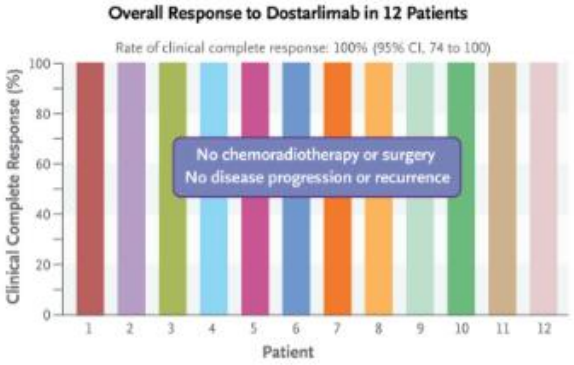
Safety: No adverse events of grade 3 or higher have occurred. The most common adverse events of grade 1 or 2 included rash or dermatitis, pruritus, fatigue, and nausea.

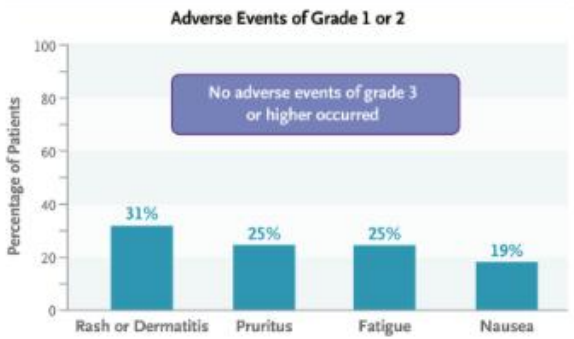
LIMITATIONS AND REMAINING QUESTIONS

- The study was small and limited to a single institution, and most of the patients were White.
- Longer-term follow-up is needed to evaluate the duration of response.

Links: Full Article | NEJM Quick Take | Editorial







CONCLUSIONS

All patients with mismatch repair–deficient, locally advanced rectal cancer who were treated with the PD-1 inhibitor dostarlimab alone for 6 months had a clinical complete response, although longer follow-up is warranted.

ORIGINAL ARTICLE

PD-1 Blockade in Mismatch Repair–Deficient, Locally Advanced Rectal Cancer

Andrea Cercek, M.D., Melissa Lumish, M.D., Jenna Sinopoli, N.P., Jill Weiss, B.A., Jinru Shia, M.D., Michelle Lamendola-Essel, D.H.Sc., Imane H. El Dika, M.D., Neil Segal, M.D., Marina Shcherba, M.D., Ryan Sugarman, M.D., Ph.D., Zsofia Stadler, M.D., Rona Yaeger, M.D., et al.

Franciscan HEALTH
CANCER CENTER

Biologic

- VEGFi did show improved response rate but with more wound and healing complications
- EGFR antibodies: did not show improved response rates

Abstracting Rectal Cancer

LESLIE WOODARD, CTR

ICRA EDUCATION CHAIR

TUMOR REGISTRY MANAGER, FRANCISCAN HEALTH SYSTEM

NOVEMBER 2023

Case #1

FOR THE PURPOSES OF TRAINING/REGISTRY CODING, WE ARE FOLLOWING THE STORE 2023 RULES, EVEN THOUGH THE CASE WAS NOT DIAGNOSED IN 2023. IF THIS WAS A CASE YOU WERE ABSTRACTING, YOU WOULD FOLLOW THE STORE MANUAL FROM THE YEAR OF DIAGNOSIS.

Presentation

- 4/9/21 Rectal bx @ Outside Facility = Adenocarcinoma, moderately well-differentiated. Negative for angiolymphatic invasion. IHC stable.
- 4/16/21 CT CAP: Circumferential rectal thickening with subtle perirectal stranding. No focal fluid collection or pelvic lymphadenopathy. No evidence for metastatic disease.
- 4/16/11 CEA: 8.7 (elevated)
- 4/23/21 Rectal cancer MRI: Tumor penetrates through surface of visceral peritoneum with no evidence for tumor invasion into pelvic organs or sacrum. T4a N2 rectal tumor with at least 7 suspicious mesorectal nodes.
- 5/12/21-8/25/21: 8 cycles FOLFOX @ my facility
- 9/20/21: Capecitabine w/ XRT @ my facility
- Radiation:

Treatment Summary:

Radiation Oncology - Course: 1 **Protocol:**

Treatment Site	Current Dose	Modality	From	To	Elapsed Days	Fx.
PTV_Pelvis initial	4,500 cGy	TOMO 6x	9/20/2021	10/22/2021	32	25
PTV_boost rectum	540 cGy	TOMO 6x	10/25/2021	10/27/2021	2	3

Presentation

- 12/1/21 Rectal cancer MRI: Compared to 04/23/2021, the patient's semiannular rectal mass is significantly decreased in size. The mass is now characterized by areas of fibrosis with small volume of suspected residual viable tumor. Tumor/fibrosis extends beyond the muscularis propria with spiculations extending to the anterior peritoneal reflection, which is not clearly involved by residual tumor. Markedly decreased size of previously enlarged suspicious mesorectal lymph nodes. No suspicious mesorectal or extra mesorectal lymph nodes are identified.
- 1/4/22 Colonoscopy: Minimal residual tumor/scar in mid rectum, otherwise clear colon.
- 1/5/22-1/8/22 Robotic-assisted laparoscopic LAR @ My Facility: Grade 2 adenocarcinoma, 1.9 cm, invades through muscularis propria into pericolorectal tissue. No LVI pr PNI. Treatment effect present (partial response, score 2). Macroscopic evaluation of mesorectum complete. Margins all negative, distance from invasive carcinoma to radial margin is 1.3 cm. 0/17 lymph nodes. No tumor deposits. ypT3 N0 M N/A.
- 3/2/22 Dr. Bhave follow-up states NED
- 9/22/23 Dr. Bhave follow-up states doing well with interval CT scan and CEA showing NED

•4/9/21 Rectal bx @ Outside Facility = Adenocarcinoma, moderately well-differentiated. Negative for angiolymphatic invasion. IHC stable.
•1/5/22 Robotic-assisted laparoscopic LAR @ My Facility: Grade 2 adenocarcinoma, 1.9 cm, invades through muscularis propria into pericolorectal tissue. No LVI pr PNI. Treatment effect present (partial response, score 2). Macroscopic evaluation of mesorectum complete. Margins all negative, distance from invasive carcinoma to radial margin is 1.3 cm. 0/17 lymph nodes. No tumor deposits. ypT3 N0 M N/A.

Date of Initial Diagnosis

- 04/09/2021

Primary Site

- C20.9

Histology

- 8140/3

Sequence Number

- 00

Laterality

- 0

Tumor Size Summary

- 999

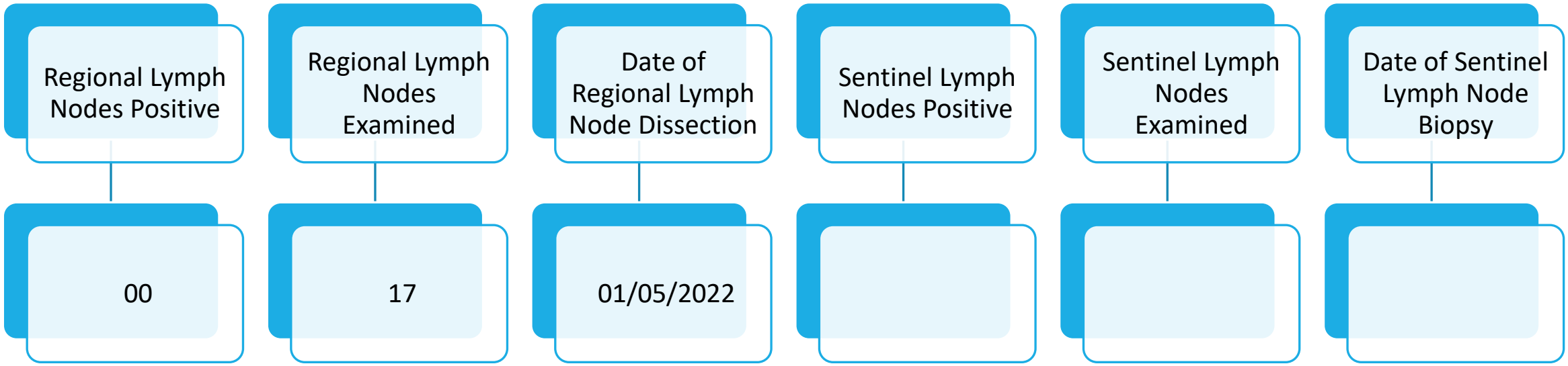
Lymphovascular Invasion

- 0

Diagnostic Confirmation

- 1

•1/5/22 Robotic-assisted laparoscopic LAR @ My Facility: Grade 2 adenocarcinoma, 1.9 cm, invades through muscularis propria into pericolorectal tissue. No LVI pr PNI. Treatment effect present (partial response, score 2). Macroscopic evaluation of mesorectum complete. Margins all negative, distance from invasive carcinoma to radial margin is 1.3 cm. 0/17 lymph nodes. No tumor deposits. ypT3 N0 M N/A.



•Diagnosed via colonoscopy w/ biopsy outside facility 4/9/21
•Chemoradiation at my facility 5/12/21-10/27/21
•Surgery at my facility 1/5/22

Class of Case

- 22

Date of First Contact

- 05/12/2021

AJCC Staging

•4/9/21 Rectal bx @ Outside Facility = Adenocarcinoma, moderately well-differentiated. Negative for angiolymphatic invasion. IHC stable.
•4/16/21 CT CAP: Circumferential rectal thickening with subtle perirectal stranding. No focal fluid collection or pelvic lymphadenopathy. No evidence for metastatic disease.
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•1/4/22 Colonoscopy: Minimal residual tumor/scar in mid rectum, otherwise clear colon.

Clinical	
Grade	2
cT	4a
cN	2b
cM	0
Stage Group	IIIC

Post Therapy Clinical	
Grade	9
ycT	3
ycN	0
ycM	0
Stage Group	N/A

•1/5/22 Robotic-assisted laparoscopic LAR @ My Facility: Grade 2 adenocarcinoma, 1.9 cm, invades through muscularis propria into pericolorectal tissue. No LVI pr PNI. Treatment effect present (partial response, score 2). Macroscopic evaluation of mesorectum complete. Margins all negative, distance from invasive carcinoma to radial margin is 1.3 cm. 0/17 lymph nodes. No tumor deposits. ypT3 N0 M N/A.

AJCC Staging

Pathological	
Grade	9
pT	
pN	
pM	
Stage Group	

Post Therapy Pathological	
Grade	2
ypT	3
ypN	0
ypM	0
Stage Group	IIA

Summary Stage

- 4/9/21 Rectal bx @ Outside Facility = Adenocarcinoma, moderately well-differentiated. Negative for angiolymphatic invasion. IHC stable.
- 4/16/21 CT CAP: Circumferential rectal thickening with subtle perirectal stranding. No focal fluid collection or pelvic lymphadenopathy. No evidence for metastatic disease.
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4 Regional by BOTH direct extension AND regional lymph node(s) involved

•4/9/21 Rectal bx @ Outside Facility = Adenocarcinoma, moderately well-differentiated. Negative for angiolymphatic invasion. IHC stable.
•4/16/11 CEA: 8.7 (elevated)
• 1/5/22 Robotic-assisted laparoscopic LAR @ My Facility: Grade 2 adenocarcinoma, 1.9 cm, invades through muscularis propria into pericolorectal tissue. No LVI pr PNI. Treatment effect present (partial response, score 2). Macroscopic evaluation of mesorectum complete. Margins all negative, distance from invasive carcinoma to radial margin is 1.3 cm. 0/17 lymph nodes. No tumor deposits. ypT3 N0 M N/A.

SSDIs

CEA PreTX Lab Value

8.7

CEA PreTX Interpretation

1

Tumor Deposits

00

Perineural Invasion

0

Circumferential Resection Margin

13.0

KRAS

9

•4/9/21 Rectal bx @ Outside Facility = Adenocarcinoma, moderately well-differentiated. Negative for angiolymphatic invasion. IHC stable.
•4/16/11 CEA: 8.7 (elevated)
• 1/5/22 Robotic-assisted laparoscopic LAR @ My Facility: Grade 2 adenocarcinoma, 1.9 cm, invades through muscularis propria into pericolorectal tissue. No LVI pr PNI. Treatment effect present (partial response, score 2). Macroscopic evaluation of mesorectum complete. Margins all negative, distance from invasive carcinoma to radial margin is 1.3 cm. 0/17 lymph nodes. No tumor deposits. ypT3 N0 M N/A.

SSDIs

Microsatellite Instability (MSI)

0

BRAF Mutational Analysis

9

NRAS Mutational Analysis

9

*Macroscopic Evaluation of the Mesorectum

30

***Not a SSDI**

Surgery

•4/9/21 Rectal bx @ Outside Facility = Adenocarcinoma, moderately well-differentiated. Negative for angiolymphatic invasion. IHC stable.
• 1/5/22-1/8/22 Robotic-assisted laparoscopic LAR @ My Facility: Grade 2 adenocarcinoma, 1.9 cm, invades through muscularis propria into pericolorectal tissue. No LVI pr PNI. Treatment effect present (partial response, score 2). Macroscopic evaluation of mesorectum complete. Margins all negative, distance from invasive carcinoma to radial margin is 1.3 cm. 0/17 lymph nodes. No tumor deposits. ypT3 N0 M N/A.

Surgical Diagnostic and Staging Procedure

02

Date of Surgical Diagnostic and Staging Procedure

04/09/2021

Reason for No Surgery of Primary Site

0

Date 1st Surgical Procedure

01/05/2022

Date of Most Definitive Surgical Resection

01/05/2022

Date of Surgical Discharge

01/08/2022

Surgery

•4/9/21 Rectal bx @ Outside Facility = Adenocarcinoma, moderately well-differentiated. Negative for angiolymphatic invasion. IHC stable.
• 1/5/22-1/8/22 Robotic-assisted laparoscopic LAR @ My Facility: Grade 2 adenocarcinoma, 1.9 cm, invades through muscularis propria into pericolorectal tissue. No LVI pr PNI. Treatment effect present (partial response, score 2). Macroscopic evaluation of mesorectum complete. Margins all negative, distance from invasive carcinoma to radial margin is 1.3 cm. 0/17 lymph nodes. No tumor deposits. ypT3 N0 M N/A.

Surgical Margins of the Primary Site

0

Scope of Regional LN Surgery

5

Rx Hosp – Surg 2023

A300

Rx Summ – Surg 2023

A300

Approach – Surgery of the Primary Site at this Facility

1

Treatment

- 4/9/21 Rectal bx @ Outside facility
- 5/12/21-8/25/21: 8 cycles FOLFOX @ my facility
- 9/20/21: Capecitabine w/ XRT @ my facility
- 1/5/22 LAR @ my facility

Date of First Course of Treatment	05/12/2021
Date Systemic Therapy Started	05/12/2021
Systemic/Surgery Sequence	2

Chemotherapy	03
Immunotherapy	00
Hormone Therapy	00
Rx Summ – Treatment Status	1

Radiation

Treatment Summary:

Radiation Oncology - Course: 1 Protocol:

Treatment Site	Current Dose	Modality	From	To	Elapsed Days	Fx.
PTV_Pelvis initial	4,500 cGy	TOMO 6x	9/20/2021	10/22/2021	32	25
PTV_boost rectum	540 cGy	TOMO 6x	10/25/2021	10/27/2021	2	3

Reason for No Radiation	0 Radiation was administered
Date Radiation Started	09/20/2021
Date Radiation Ended	10/27/2021
Radiation Treatment Discontinued Early	01 Radiation treatment completed as prescribed
Radiation Course Total Dose	005040
Number of Phases of Radiation Treatment	02

Phase I

Treatment Summary:

Radiation Oncology - Course: 1 Protocol:

Treatment Site	Current Dose	Modality	From	To	Elapsed Days	Fx.
PTV_Pelvis initial	4,500 cGy	TOMO 6x	9/20/2021	10/22/2021	32	25
PTV_boost rectum	540 cGy	TOMO 6x	10/25/2021	10/27/2021	2	3

Radiation Primary Treatment Volume	54 Rectum
Radiation to Draining Lymph Nodes	06 Pelvic lymph nodes
Radiation Treatment Modality	02 External beam, photons
External beam Radiation Planning Technique	05 Intensity modulated therapy
Dose per Fraction	00180
Number of Fractions	025
Total Dose	004500

Phase II

Treatment Summary:

Radiation Oncology - Course: 1 Protocol:

Treatment Site	Current Dose	Modality	From	To	Elapsed Days	Fx.
PTV_Pelvis initial	4,500 cGy	TOMO 6x	9/20/2021	10/22/2021	32	25
PTV_boost rectum	540 cGy	TOMO 6x	10/25/2021	10/27/2021	2	3

Radiation Primary Treatment Volume	54 Rectum
Radiation to Draining Lymph Nodes	00
Radiation Treatment Modality	02 External beam, photons
External beam Radiation Planning Technique	05 Intensity modulated therapy
Dose per Fraction	00180
Number of Fractions	003
Total Dose	000540

Phase III

Radiation Primary Treatment Volume

Radiation to Draining Lymph Nodes

Radiation Treatment Modality

External beam Radiation Planning Technique

Dose per Fraction

Number of Fractions

Total Dose

LEAVE BLANK

Outcomes

•1/5/22-1/8/22 Robotic-assisted laparoscopic LAR @ My Facility: Grade 2 adenocarcinoma, 1.9 cm, invades through muscularis propria into pericolorectal tissue. No LVI pr PNI. Treatment effect present (partial response, score 2). Macroscopic evaluation of mesorectum complete. Margins all negative, distance from invasive carcinoma to radial margin is 1.3 cm. 0/17 lymph nodes. No tumor deposits. ypT3 N0 M N/A.
•3/2/22 Dr. Bhave follow-up states NED
•9/22/23 Dr. Bhave follow-up states doing well with interval CT scan and CEA showing NED

Date of First Recurrence	
Type of First Recurrence	00
Date of Last Cancer (tumor) Status	01/05/2022
Cancer Status	1
Vital Status	1

Case #2

FOR THE PURPOSES OF TRAINING/REGISTRY CODING, WE ARE FOLLOWING THE STORE 2023 RULES, EVEN THOUGH THE CASE WAS NOT DIAGNOSED IN 2023. IF THIS WAS A CASE YOU WERE ABSTRACTING, YOU WOULD FOLLOW THE STORE MANUAL FROM THE YEAR OF DIAGNOSIS.

Presentation

- 9/30/21 Screening Colonoscopy @ Outside Hospital = In the distal rectum there was an ulcerated sizable approximately 3 cm mass with a central ulceration. The edges were friable, and the central area appeared necrotic. This is consistent with a rectal cancer.
- 9/30/21 Biopsy of rectal mass @ Outside Hospital = Fragments of tubular adenoma, positive for high-grade dysplasia
- 10/11/21 CT CAP **[Clinical indication: Malignant neoplasm of rectum]** @ Outside Hospital = Asymmetric rectal wall thickening raising concern for rectal neoplasm given the current setting; no destructive fatty infiltration or pelvic lymphadenopathy. Negative chest CT.
- 10/14/21 Sigmoidoscopy w/ rectal bx @ My Facility = Superficial disrupted fragments of adenomatous epithelium with at least high-grade dysplasia. The patient's clinical history of a "rectal mass clinically suspicious for rectal cancer" is noted. Histologic sections demonstrate only superficial fragments of glandular type mucosa with adenomatous change and high-grade dysplasia. No definitive evidence of invasion and/or desmoplastic response is identified in the sections examined.
- 10/15/21 MRI Pelvis = T2/early T3 rectal cancer. No tumor deposits or lymph nodes.
- Surgeon notes: Stage II rectal cancer based on all current available imaging.
- 11/3/21 Consult @ Outside facility #2 = Rectal mass concerning for rectal adenocarcinoma on endoscopic exam. Repeated biopsy. MRI consistent with T3 N0 disease, recommend TNT.
- 11/3/21 Rectal mass bx @ Outside facility #2 = Invasive adenocarcinoma, well differentiated, arising from tubulovillous adenoma. Mismatch Repair Protein Immunohistochemistry = Normal expression of MLH1, MSH2, MSH6, and PMS2
- 11/30/21 CEA = 2.4 (normal)

Presentation

- FOLFOX 11/17/21-2/23/22 for T3 rectal cancer @ Outside facility
- Xeloda + radiation 3/28/22-5/4/22 @ Outside facility. No radiation details available.
- 6/22/22 Sigmoidoscopy @ My facility = Flat scar noted in the rectum, smooth, consistent with complete clinical response.
- 6/22/22 Post-treatment MRI = No residual tumor. Discussed watch ‘n wait vs. surgery. Plan on repeat FFS and MRI in 3-4 months.

Date of Initial Diagnosis

- 09/30/2021

Primary Site

- C20.9

Histology

- 8140/3

Sequence Number

- 00

Laterality

- 0

Tumor Size Summary

- 030

Lymphovascular Invasion

- 9

Diagnostic Confirmation

- 1

- 9/30/21 Screening Colonoscopy @ Outside Hospital = In the distal rectum there was an ulcerated sizable approximately 3 cm mass with a central ulceration. The edges were friable, and the central area appeared necrotic. This is consistent with a rectal cancer.
- 9/30/21 Biopsy of rectal mass @ Outside Hospital = Fragments of tubular adenoma, positive for high-grade dysplasia
- 10/11/21 CT CAP **[Clinical indication: Malignant neoplasm of rectum]** @ Outside Hospital = Asymmetric rectal wall thickening raising concern for rectal neoplasm given the current setting; no destructive fatty infiltration or pelvic lymphadenopathy. Negative chest CT.
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- 9/30/21 Screening Colonoscopy @ Outside Hospital = In the distal rectum there was an ulcerated sizable approximately 3 cm mass with a central ulceration. The edges were friable, and the central area appeared necrotic. This is consistent with a rectal cancer.
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- Xeloda + radiation 3/28/22-5/4/22 @ Outside facility. No radiation details available.
- 6/22/22 Sigmoidoscopy @ My facility = Flat scar noted in the rectum, smooth, consistent with complete clinical response.
- 6/22/22 Post-treatment MRI = No residual tumor. Discussed watch ‘n wait vs. surgery. Plan on repeat FFS and MRI in 3-4 months.

Regional Lymph Nodes Positive	Regional Lymph Nodes Examined	Date of Regional Lymph Node Dissection	Sentinel Lymph Nodes Positive	Sentinel Lymph Nodes Examined	Date of Sentinel Lymph Node Biopsy
98	00				

Class of Case

- 30

Date of First Contact

- 10/14/2021

- 9/30/21 Screening Colonoscopy @ Outside Hospital = In the distal rectum there was an ulcerated sizable approximately 3 cm mass with a central ulceration. The edges were friable, and the central area appeared necrotic. This is consistent with a rectal cancer.
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https://cancerbulletin.facs.org/forums/node/111546
https://cancerbulletin.facs.org/forums/node/130846#post130877

AJCC Staging

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- 10/11 conce
- 10/14 dyspl only s of inv
- 10/15
- Surge
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aising st CT.

high-grade onstrate e

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- 11/3/21 Rectal mass bx @ Outside facility #2 = Invasive adenocarcinoma, well differentiated, arising from tubulovillous adenoma. Mismatch Repair Protein Immunohistochemistry = Normal expression of MLH1, MSH2, MSH6, and PMS2

Clinical	
Grade	1
cT	3
cN	0
cM	0
Stage Group	IIA

Post Therapy Clinical	
Grade	9
ycT	0
ycN	0
ycM	0
Stage Group	N/A

AJCC Staging

- FOLFOX 11/17/21-2/23/22 for T3 rectal cancer @ Outside facility
- Xeloda + radiation 3/28/22-5/4/22 @ Outside facility. No radiation details available.
- 6/22/22 Sigmoidoscopy @ My facility = Flat scar noted in the rectum, smooth, consistent with complete clinical response.
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Pathological	
Grade	9
pT	
pN	
pM	
Stage Group	

Post Therapy Pathological	
Grade	
ypT	
ypN	
ypM	
Stage Group	

10/15/21 MRI Pelvis = T2/early T3 low rectal cancer (the muscularis propria appears invaded and indistinct at several sites. Depth of extramural invasion is less than 1 mm). No tumor deposits or lymph nodes.

Summary Stage

1

- 9/30/21 Screening Colonoscopy @ Outside Hospital = In the distal rectum there was an ulcerated sizable approximately 3 cm mass with a central ulceration. The edges were friable, and the central area appeared necrotic. This is consistent with a rectal cancer.
- 9/30/21 Biopsy of rectal mass @ Outside Hospital = Fragments of tubular adenoma, positive for high-grade dysplasia
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- 10/15/21 MRI Pelvis = T2/early T3 rectal cancer. No tumor deposits or lymph nodes.
- Surgeon notes: Stage II rectal cancer based on all current available imaging.
- 11/3/21 Consult @ Outside facility #2 = Rectal mass concerning for rectal adenocarcinoma on endoscopic exam. Repeated biopsy. MRI consistent with T3 N0 disease, recommend TNT.
- 11/3/21 Rectal mass bx @ Outside facility #2 = Invasive adenocarcinoma, well differentiated, arising from tubulovillous adenoma. Mismatch Repair Protein Immunohistochemistry = Normal expression of MLH1, MSH2, MSH6, and PMS2
- 11/30/21 CEA = 2.4 (normal)

- FOLFOX 11/17/21-2/23/22 for T3 rectal cancer @ Outside facility
- Xeloda + radiation 3/28/22-5/4/22 @ Outside facility. No radiation details available.
- 6/22/22 Sigmoidoscopy @ My facility = Flat scar noted in the rectum, smooth, consistent with complete clinical response.
- 6/22/22 Post-treatment MRI = No residual tumor. Discussed watch ‘n wait vs. surgery. Plan on repeat FFS and MRI in 3-4 months.

SSDIs

CEA PreTX Lab Value

- XXXX.9

CEA PreTX Interpretation

- 9

Tumor Deposits

- X9

Perineural Invasion

- 9

Circumferential Resection Margin

- XX.7

KRAS

- 9

- 9/30/21 Screening Colonoscopy @ Outside Hospital = In the distal rectum there was an ulcerated sizable approximately 3 cm mass with a central ulceration. The edges were friable, and the central area appeared necrotic. This is consistent with a rectal cancer.
- 9/30/21 Biopsy of rectal mass @ Outside Hospital = Fragments of tubular adenoma, positive for high-grade dysplasia
- 10/11/21 CT CAP **[Clinical indication: Malignant neoplasm of rectum]** @ Outside Hospital = Asymmetric rectal wall thickening raising concern for rectal neoplasm given the current setting; no destructive fatty infiltration or pelvic lymphadenopathy. Negative chest CT.
- 10/14/21 Sigmoidoscopy w/ rectal bx @ My Facility = Superficial disrupted fragments of adenomatous epithelium with at least high-grade dysplasia. The patient's clinical history of a "rectal mass clinically suspicious for rectal cancer" is noted. Histologic sections demonstrate only superficial fragments of glandular type mucosa with adenomatous change and high-grade dysplasia. No definitive evidence of invasion and/or desmoplastic response is identified in the sections examined.
- 10/15/21 MRI Pelvis = T2/early T3 rectal cancer. No tumor deposits or lymph nodes.
- Surgeon notes: Stage II rectal cancer based on all current available imaging.
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SSDIs

Microsatellite Instability (MSI)

- 0

BRAF Mutational Analysis

- 9

NRAS Mutational Analysis

- 9

*Macroscopic Evaluation of the Mesorectum

- 00

***Not a SSDI**

Surgery

•9/30/21 Biopsy of rectal mass @ Outside Hospital = Fragments of tubular adenoma, positive for high-grade dysplasia
•10/14/21 Sigmoidoscopy w/ rectal bx @ My Facility = Superficial disrupted fragments of adenomatous epithelium with at least high-grade dysplasia. The patient's clinical history of a "rectal mass clinically suspicious for rectal cancer" is noted. Histologic sections demonstrate only superficial fragments of glandular type mucosa with adenomatous change and high-grade dysplasia. No definitive evidence of invasion and/or desmoplastic response is identified in the sections examined.
•11/3/21 Rectal mass bx @ Outside facility #2 = Invasive adenocarcinoma, well differentiated, arising from tubulovillous adenoma. Mismatch Repair Protein Immunohistochemistry = Normal expression of MLH1, MSH2, MSH6, and PMS2

Surgical Diagnostic and Staging Procedure

02

Date of Surgical Diagnostic and Staging Procedure

11/03/2021

Reason for No Surgery of Primary Site

1

Date 1st Surgical Procedure

Date of Most Definitive Surgical Resection

Date of Surgical Discharge

Surgery

- FOLFOX 11/17/21-2/23/22 for T3 rectal cancer @ Outside facility
- Xeloda + radiation 3/28/22-5/4/22 @ Outside facility. No radiation details available.
- 6/22/22 Sigmoidoscopy @ My facility = Flat scar noted in the rectum, smooth, consistent with complete clinical response.
- 6/22/22 Post-treatment MRI = No residual tumor. Discussed watch 'n wait vs. surgery. Plan on repeat FFS and MRI in 3-4 months.

Surgical Margins of the Primary Site

8

Scope of Regional LN Surgery

0

Rx Hosp – Surg 2023

A000

Rx Summ – Surg 2023

A000

Approach – Surgery of the Primary Site at this Facility

0

Treatment

- FOLFOX 11/17/21-2/23/22 for T3 rectal cancer @ Outside facility
- Xeloda + radiation 3/28/22-5/4/22 @ Outside facility. No radiation details available.
- 6/22/22 Sigmoidoscopy @ My facility = Flat scar noted in the rectum, smooth, consistent with complete clinical response.
- 6/22/22 Post-treatment MRI = No residual tumor. Discussed watch ‘n wait vs. surgery. Plan on repeat FFS and MRI in 3-4 months.

Date of First Course of Treatment	11/17/2021
Date Systemic Therapy Started	11/17/2021
Systemic/Surgery Sequence	0
Chemotherapy	03
Immunotherapy	00
Hormone Therapy	00
Rx Summ – Treatment Status	1

Radiation

Contacted outside facility CTR for details:
3/28/22 to 5/4/22: 3D Conformal/Photons to rectum/pelvis, total 5040 cGy in 28 fx. Initial dose of 4500 cGy in 25 fx to rectum/pelvis, boost to rectum of 540 cGy in 3 fx.

Reason for No Radiation	0 Radiation was administered
Date Radiation Started	03/28/2022
Date Radiation Ended	05/04/2022
Radiation Treatment Discontinued Early	01 Radiation treatment completed as prescribed
Radiation Course Total Dose	005040
Number of Phases of Radiation Treatment	002

Phase I

Contacted outside facility CTR for details:
3/28/22 to 5/4/22: 3D Conformal/Photons to rectum/pelvis, total 5040 cGy in 28 fx. Initial dose of 4500 cGy in 25 fx to rectum/pelvis, boost to rectum of 540 cGy in 3 fx.

Radiation Primary Treatment Volume	54 Rectum
Radiation to Draining Lymph Nodes	06 Pelvic Nodes
Radiation Treatment Modality	02 External beam, photons
External beam Radiation Planning Technique	04 Conformal or 3-D conformal therapy
Dose per Fraction	00180
Number of Fractions	025
Total Dose	004500

Phase II

Contacted outside facility CTR for details:
3/28/22 to 5/4/22: 3D Conformal/Photons to rectum/pelvis, total 5040 cGy in 28 fx. Initial dose of 4500 cGy in 25 fx to rectum/pelvis, boost to rectum of 540 cGy in 3 fx.

Radiation Primary Treatment Volume	54 Rectum
Radiation to Draining Lymph Nodes	00 No radiation treatment to lymph nodes
Radiation Treatment Modality	02 External beam, photons
External beam Radiation Planning Technique	04 Conformal or 3-D conformal therapy
Dose per Fraction	00180
Number of Fractions	003
Total Dose	000540

Phase III

Radiation Primary Treatment Volume

Radiation to Draining Lymph Nodes

Radiation Treatment Modality

External beam Radiation Planning Technique

Dose per Fraction

Number of Fractions

Total Dose

LEAVE BLANK

Outcomes

- FOLFOX 11/17/21-2/23/22 for T3 rectal cancer @ Outside facility
- Xeloda + radiation 3/28/22-5/4/22 @ Outside facility. No radiation details available.
- 6/22/22 Sigmoidoscopy @ My facility = Flat scar noted in the rectum, smooth, consistent with complete clinical response.
- 6/22/22 Post-treatment MRI = No residual tumor. Discussed watch ‘n wait vs. surgery. Plan on repeat FFS and MRI in 3-4 months.

Date of First Recurrence	
Type of First Recurrence	00
Date of Last Cancer (tumor) Status	06/22/2022
Cancer Status	1
Vital Status	1

Use Your Resources!

STORE

CTR Guide for Coding Radiation

Physicians

CAnswer Forum

Webinars

Questions?