



Colorectal Cancer: A Minimalist Approach

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Disclosures

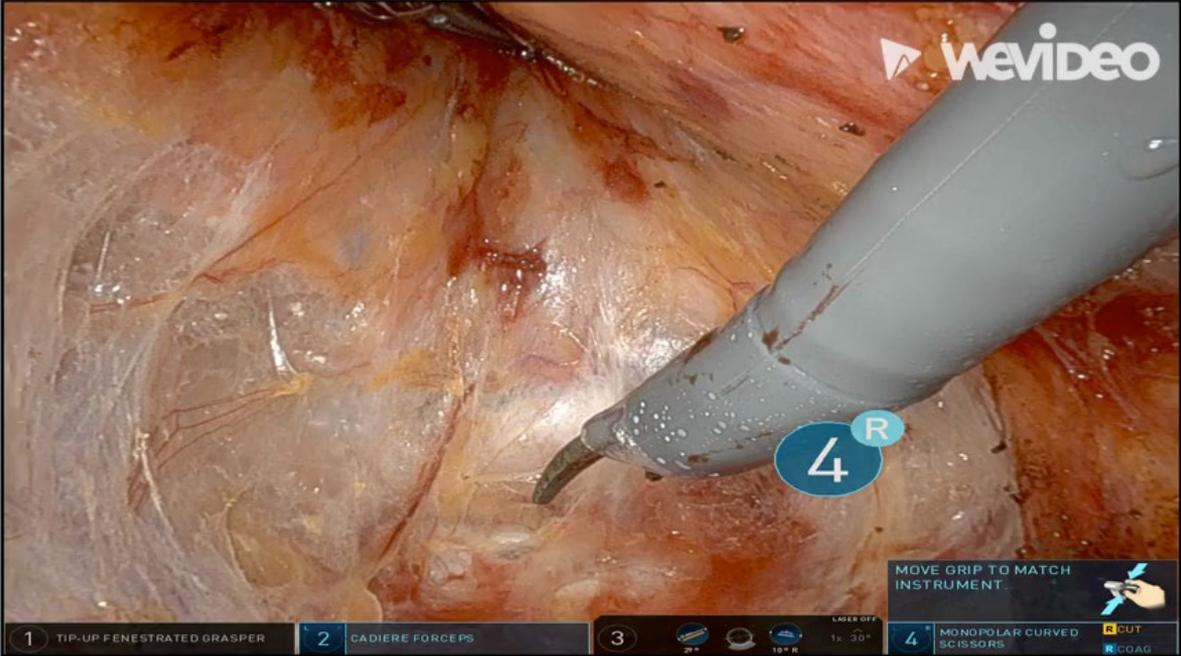
Consultant for
Intuitive when I
was at Johns
Hopkins Hospital.



Objectives

1. Robotic surgery in colorectal cancer
2. Watch and Wait Approach to Rectal Cancer

Robotic total mesorectal excision



Effect of Robotic-Assisted vs Conventional Laparoscopic Surgery on Risk of Conversion to Open Laparotomy Among Patients Undergoing Resection for Rectal Cancer: The ROLARR Randomized Clinical Trial

David Jayne¹, Alessio Pigazzi², Helen Marshall³, Julie Croft³, Neil Corrigan³, Joanne Copeland³, Phil Quirke⁴, Nick West⁴, Tero Rautio⁵, Niels Thomassen⁶, Henry Tilney⁷, Mark Gudgeon⁷, Paolo Pietro Bianchi⁸, Richard Edlin⁹, Claire Hulme¹⁰, Julia Brown³

- Randomized clinical trial: robotic-assisted vs conventional laparoscopic surgery => open conversion rates
 - 29 sites, 10 countries, 40 surgeons
 - Recruitment: 1/7/2011-9/30/2014
- 471 patients with rectal adenocarcinoma
 - Robotic assisted: 237 patients
 - Laparoscopic: 234 patients
- f/u: 30 days, 6 months
- No significant reduction in conversion to laparotomy

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Table 3. Secondary End Points by Treatment Group

End Point	No./Total No. (%)		Unadjusted Risk Difference (95% CI), %	Adjusted Odds Ratio (95% CI) ^a	P Value
	Conventional Laparoscopic Surgery	Robotic-Assisted Laparoscopic Surgery			
CRM ⁺ ^b	14/224 (6.3)	12/235 (5.1)	1.2 (-3.1 to 5.4)	0.78 (0.35 to 1.76)	.56
Mesorectal area = mesorectal plane	173/223 (77.6)	178/233 (76.4)	1.2 (-6.5 to 8.9)	0.94 (0.56 to 1.57)	.14
Intraoperative complication	34/230 (14.8)	36/236 (15.3)	-0.5 (-6.0 to 7.0)	1.02 (0.60 to 1.74)	.94
Postoperative complication within 30 d of operation	73/230 (31.7)	78/236 (33.1)	-1.3 (-9.8 to 7.2)	1.04 (0.69 to 1.58)	.84
Postoperative complication >30 d and ≤6 mo after operation	38/230 (16.5)	34/236 (14.4)	2.1 (-4.5 to 8.7)	0.72 (0.41 to 1.26)	.25
Mortality within 30 d of operation ^c	2/230 (0.9)	2/236 (0.8)	0.02 (-1.7 to 1.7)	NA	NA

Abbreviations: CRM+, circumferential resection margin positivity; NA, not applicable.

^a Adjusted for sex, body mass index class, preoperative radiotherapy, intended procedure, and operating surgeon.

^b Defined as tumor cells within 1 mm of the circumferential resection margin on histological analysis.

^c Adjusted analysis was not performed for mortality within 30 days of operation due to the small number of events.

Robot-assisted Versus Laparoscopic Surgery for Rectal Cancer: A Phase II Open Label Prospective Randomized Controlled Trial

Min Jung Kim ¹, Sung Chan Park ¹, Ji Won Park ^{1 2}, Hee Jin Chang ¹, Dae Yong Kim ¹,
Byung-Ho Nam ³, Dae Kyung Sohn ¹, Jae Hwan Oh ¹

- Randomized 1:1: robotic vs laparoscopic
 - South Korea, 3 surgeons
 - Recruitment: 2/21/2012-3/11/2015
- Primary outcome: quality of TME
- 139 patients
 - Robotic: 66
 - Laparoscopic: 73

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[Robot-assisted Versus Laparoscopic Surgery for Rectal Cancer: A Phase II Open Label Prospective Randomized Controlled Trial](#)

Kim, Min Jung; Park, Sung Chan; Park, Ji Won; Chang, Hee Jin; Kim, Dae Yong; Nam, Byung-Ho; Sohn, Dae Kyung; Oh, Jae Hwan
Annals of Surgery 267(2):243-251, February 2018.
doi: 10.1097/SLA.0000000000002321

	RG (n = 66)	LG (n = 73)	P
Tumor size, cm, median (range)	2.5 (0–6.0)	2.1 (0–11.0)	0.84
Number of harvested lymph nodes			0.04
Median	18.0	15.0	
Range	7.0–59.0	4.0–40.0	
<12, n (%)	6 (9.1)	19 (26.0)	0.009
≥12, n (%)	60 (90.9)	54 (74.0)	
Tumor differentiation, n (%)			0.412
Well differentiated	9 (13.6)	8 (11.0)	
Moderately differentiated	53 (80.3)	64 (86.2)	
Poorly differentiated	3 (4.6)	1 (1.4)	
Mucinous	1 (1.5)	0 (1.4)	
Tumor Regression Grade Scale, n (%)*			0.99
1	11 (16.7)	11 (15.1)	
2	28 (42.4)	31 (42.5)	
3	8 (12.1)	10 (13.7)	
4	5 (7.6)	6 (8.2)	
p/ypT classification, n (%)			0.956
T0	5 (7.6)	6 (8.2)	
Tis	2 (3.0)	4 (5.5)	
T1	8 (12.1)	7 (9.6)	
T2	17 (25.8)	18 (24.6)	
T3	30 (45.5)	36 (49.3)	
T4a	2 (3.0)	1 (1.4)	
T4b	2 (3.0)	1 (1.4)	
p/ypN classification, n (%)			0.713
N0	46 (69.7)	56 (76.7)	
N1a	9 (13.7)	5 (6.9)	
N1b	7 (10.6)	6 (8.2)	
N1c	2 (3.0)	2 (2.7)	
N2a	2 (3.0)	3 (4.1)	
N2b	0 (0)	1 (1.4)	
Proximal resection margin, cm, median (range)	12.3 (4.7–35.8)	13.2 (6.8–29.0)	0.727
Distal resection margin, cm, median (range)	1.5 (0.04–6.7)	0.7 (0–2.5)	0.11
Radial resection margin, cm, median (range)	0.7 (0–2.5)	0.7 (0–1.8)	0.531
Circumferential resection margin, n (%)†			0.999
Positive (≤1 mm)	4 (6.1)	4 (5.5)	
Negative (>1 mm)	61 (92.4)	68 (93.2)	
Quality of TME as rated by pathologist, n (%)			0.599
Complete	53 (80.3)	57 (78.1)	
Nearly complete	12 (18.2)	16 (21.9)	
Incomplete	1 (1.5)	0 (0)	

Postoperative Pathologic Outcomes

*Data from patients with preoperative CRT or chemotherapy.

†One patient in each group had a peritonealized tumor.

CRT indicates chemoradiotherapy; TME, total mesorectal excision.

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Postoperative Pathologic Outcomes

Watch and Wait: Rectal Cancer Organ Preservation



CLINICAL STAGE

TOTAL NEOADJUVANT THERAPY

PRIMARY TREATMENT

T3, N any with involved or threatened CRM (by MRI)ⁿ;
T4, N any or Locally unresectable or medically inoperable

Long-course chemo/RT^{q,r}
• Capecitabine^p or infusional 5-FU^p
or
Short-course RT^{r,u}

or

Chemotherapy (12–16 wk)
• FOLFOX or CAPEOX
• Consider FOLFIRINOX (for T4 N+)

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• Consider FOLFIRINOX (for T4, N+)

Long-course chemo/RT^{q,r}
• Capecitabine^p or infusional 5-FU^p
or
Short-course RT^{r,u}

Restaging^c

Restaging^c

Transabdominal resection^{i,v,x}

Resection contraindicated

Transabdominal resection^{i,v,x}

Resection contraindicated

Surveillance (REC-11)

Systemic therapy^w (REC-F)

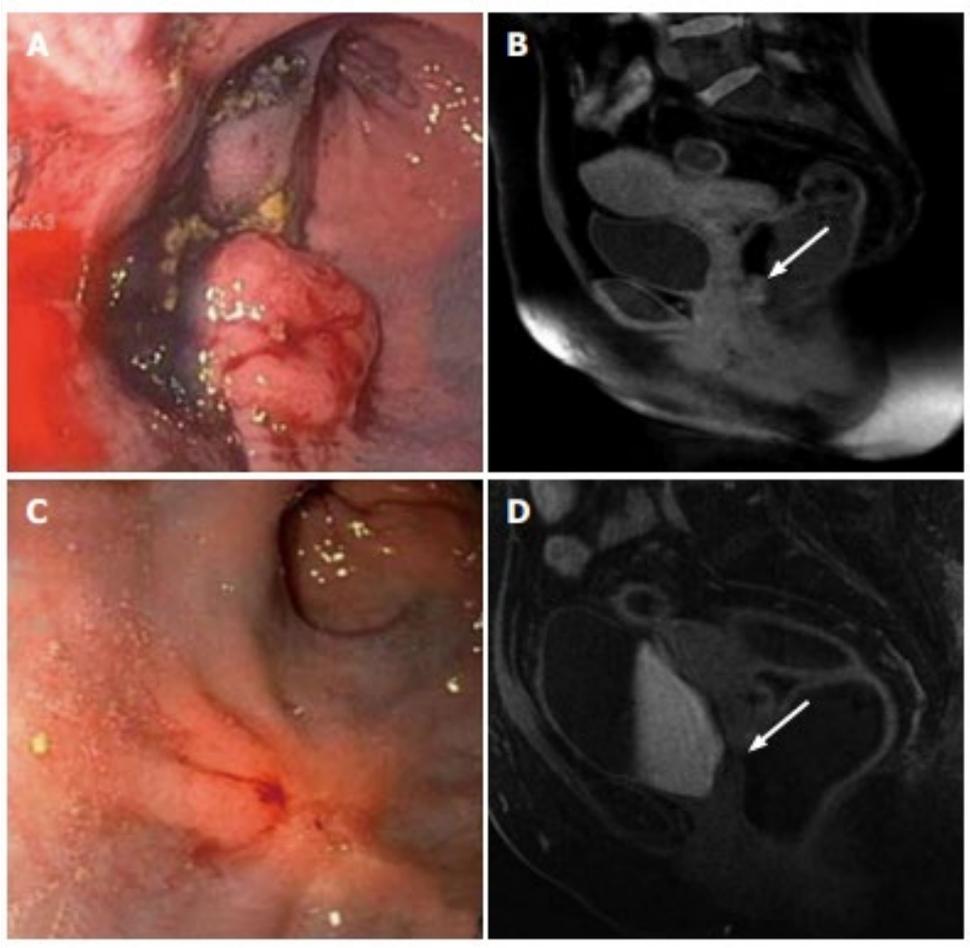
Surveillance (REC-11)

Systemic therapy^w (REC-F)

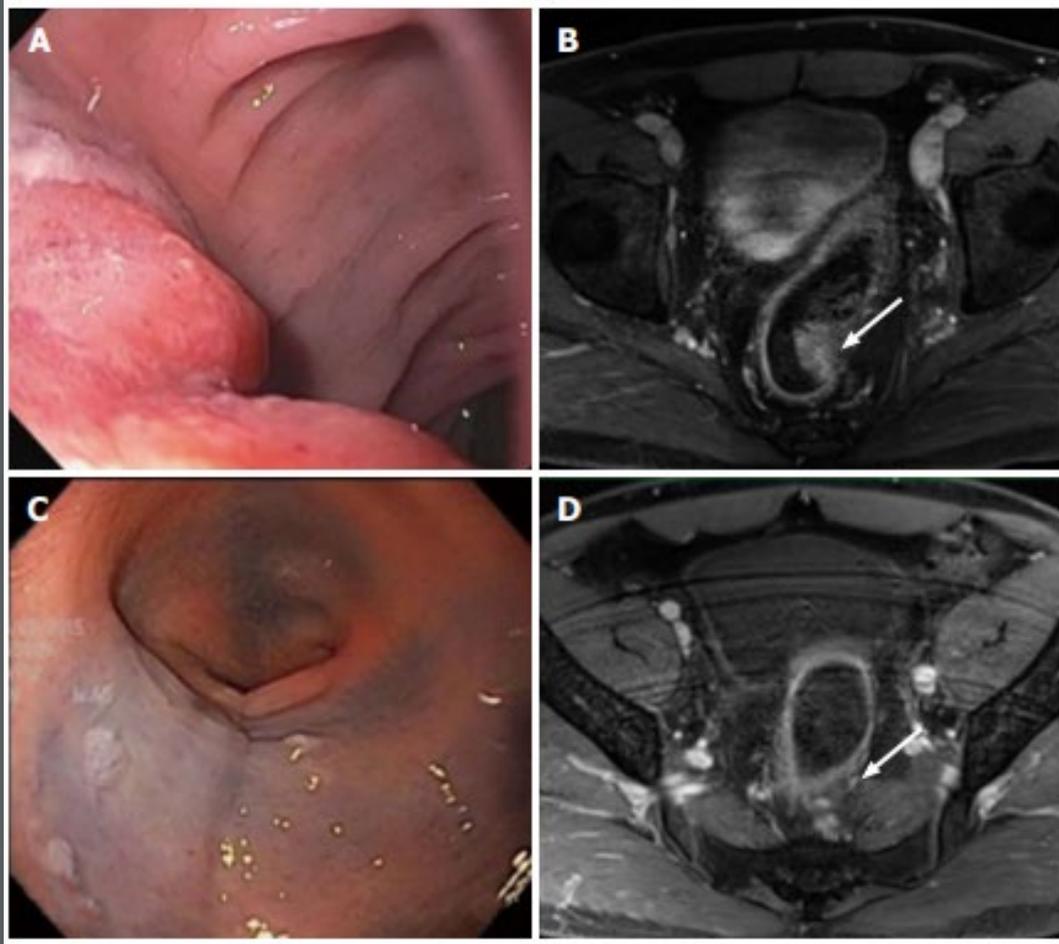
Table 2 Memorial Sloan Kettering Regression Schema

	Complete Response	Near Complete Response	Incomplete Response
Endoscopy	Flat, white scar Telangiectasia No ulcer No nodularity	Irregular mucosa Small mucosal nodules or minor mucosal abnormality Superficial ulceration Mild persisting erythema of the scar	Visible tumor
Digital Rectal Exam	Normal	Smooth induration or minor mucosal abnormalities	Palpable tumor nodules
MRI-T2W	Only dark T2 signal, no intermediate T2 signal AND No visible lymph nodes	Mostly dark T2 signal, some remaining intermediate signal AND/OR Partial regression of lymph nodes	More intermediate than dark T2 signal, no T2 scar AND/OR No regression of lymph nodes
MRI-DW	No visible tumor on B800-B1000 signal AND/OR Lack of or low signal on ADC map Uniform, linear signal in wall above tumor is ok	Significant regression of signal on B800-B1000 AND/OR Minimal or low residual signal on ADC map	Insignificant regression of signal on B800-B1000 AND/OR Obvious low signal on ADC map

Clinical Incomplete Response



Clinical Complete Response



Nonoperative Rectal Cancer Management With Short-Course Radiation Followed by Chemotherapy: A Nonrandomized Control Trial

Hyun Kim¹, Katrina Pedersen², Jeffrey R Olsen³, Matthew G Mutch⁴, Re-I Chin⁵, Sean C Glasgow⁴, Paul E Wise⁴, Matthew L Silveira⁴, Benjamin R Tan², Andrea Wang-Gillam², Kian-Huat Lim², Rama Suresh², Manik Amin², Yi Huang⁵, Lauren E Henke⁵, Haeseong Park², Matthew A Ciorba⁶, Shahed Badiyan⁵, Parag J Parikh⁷, Michael C Roach⁸, Steven R Hunt³

- Treatment
 - 25 Gy in 5 fractions
 - FOLFOX x 8 cycles or CAPOX x 5 cycles
- June 2016-March 2019: 19 patients
- Treatment with SCRT and chemotherapy resulted in high cCR rate, intact anorectal function, and no severe late effects

Surveillance Protocol: NCCN

(In addition to CT C/A/P, CEA, colonoscopy)

- DRE
- Proctoscopy
 - Every 3-4 months x 2 years
 - Then every 6 months for a total of 5 years
- Rectal cancer protocol MRI
 - Every 6 months for at least 3 years to monitor for extraluminal local recurrence
 - Then annually for a total of 5 years (OHSU)

ReSARCh

(Rectal Sparing Approach after preroperative Radio-and/or Chemotherapy)

Trial

Rectal Sparing Approach After Neoadjuvant Therapy in Patients With Rectal Cancer: The Preliminary Results of the ReSARCh Trial

Prospective Observational Trial
NCT02710812



17
Italian Hospitals



160
patients
♂104 ♀56



Rectal cancer after
neoadjuvant therapy,
fit for TME surgery

12-Weeks Restaging



64
Major
Clinical Response



96
Complete
Clinical Response

24-Months Median Follow-Up



98
Local Excision

3 Clavien-Dindo \geq 3
26 completion TME required
11 completion TME performed
10 no residual cancer at histopathology



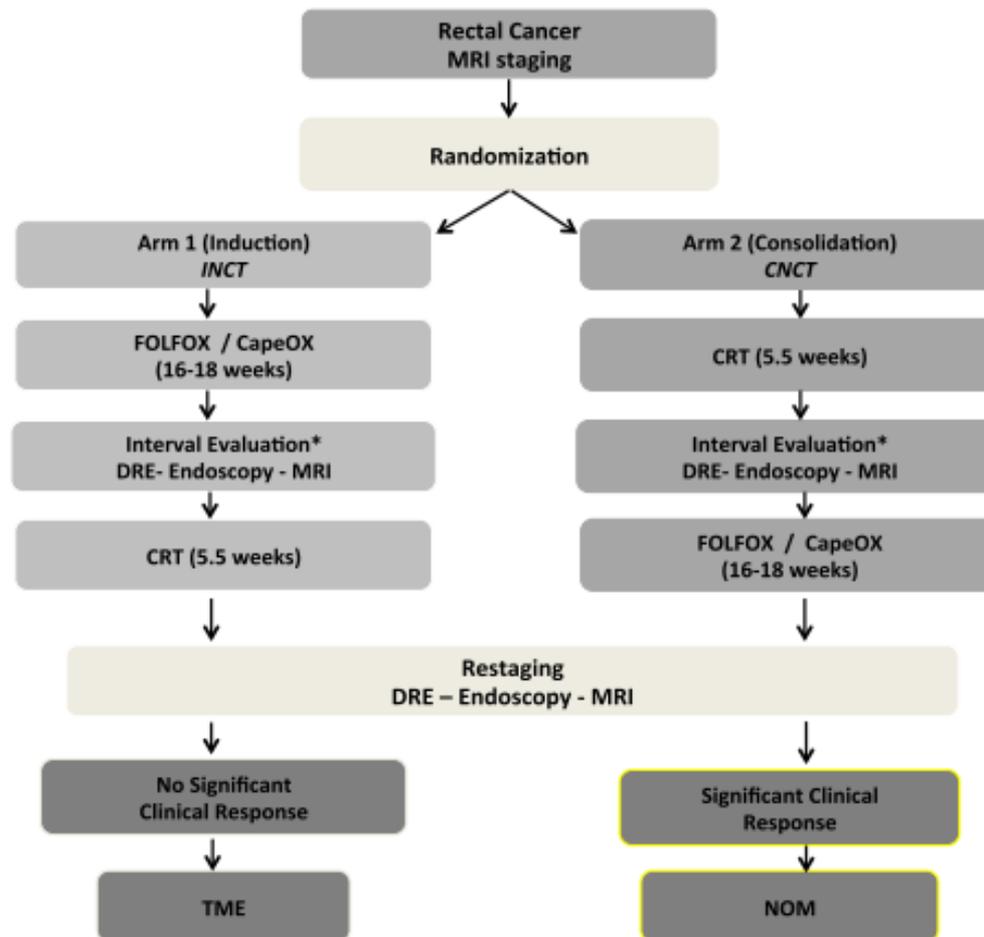
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Watch-and-Wait

Marchegiani et al., *Ann Surg Oncol*.
Visual Abstract by @GayaSpolverato for @AnnSurgOncol

ANNALS OF
SURGICAL
ONCOLOGY

Organ Preservation in Rectal Adenocarcinoma (OPRA): ongoing

- Objective: Phase II randomized controlled trial, multi-institutional : total neoadjuvant therapy and selective non-operative management in locally advanced rectal cancer



*Patients with tumor progression at the interval evaluation will be treated according to standard of care.

Fig. 1 Trial schema. MSKCC-based multi-institutional, Phase II trial schema underway to test the feasibility of incorporating a NOM approach to the multimodality treatment of rectal cancer. This study will evaluate the 3-year DFS in LARC patients treated with CRT plus induction or consolidation chemotherapy and TME or NOM (<https://clinicaltrials.gov/ct2/show/NCT02008656?term=NCT02008656&rank=1>)

A scenic view of a cable car system over a forested hillside. In the foreground, a metal railing with a mesh fence runs across the frame. A cable car is suspended from cables on the left side. In the background, a large, modern building with a glass facade is visible, surrounded by dense green trees. The sky is clear and blue.

Thank you!
Questions??