

Novità per un percorso preferenziale nelle strategie diagnostico-terapeutiche del cancro colorettales

“Le opzioni chirurgiche nel cancro del retto”

Francesco Bianco

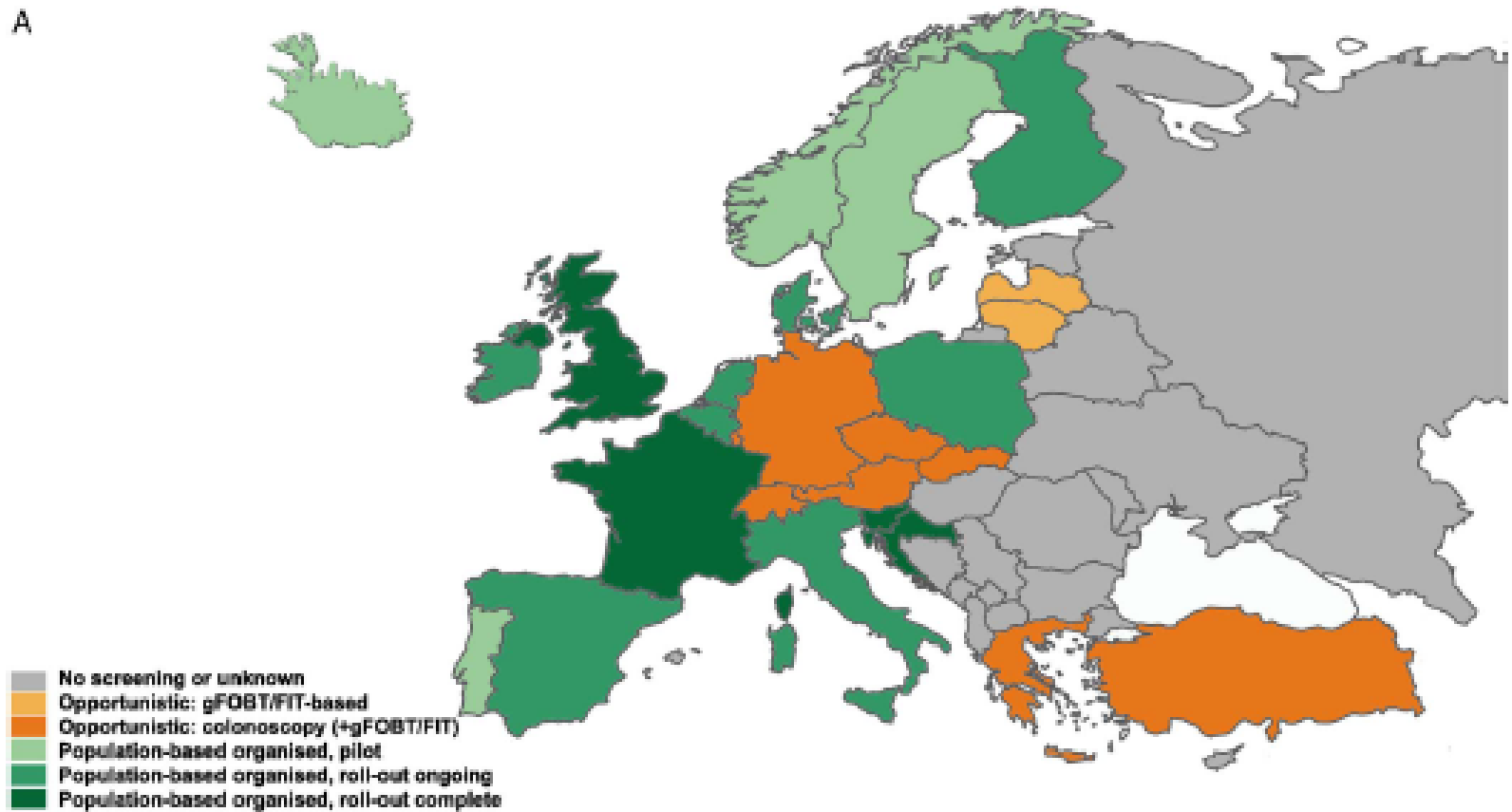
Div Chirurgia Oncologica Addominale
ad indirizzo generale



Istituto Nazionale Tumori
Fondazione G. Pascale

EUROPEAN COLORECTAL CANCER SCREENING PROGRAMS

A



Patients classification for emerging issues

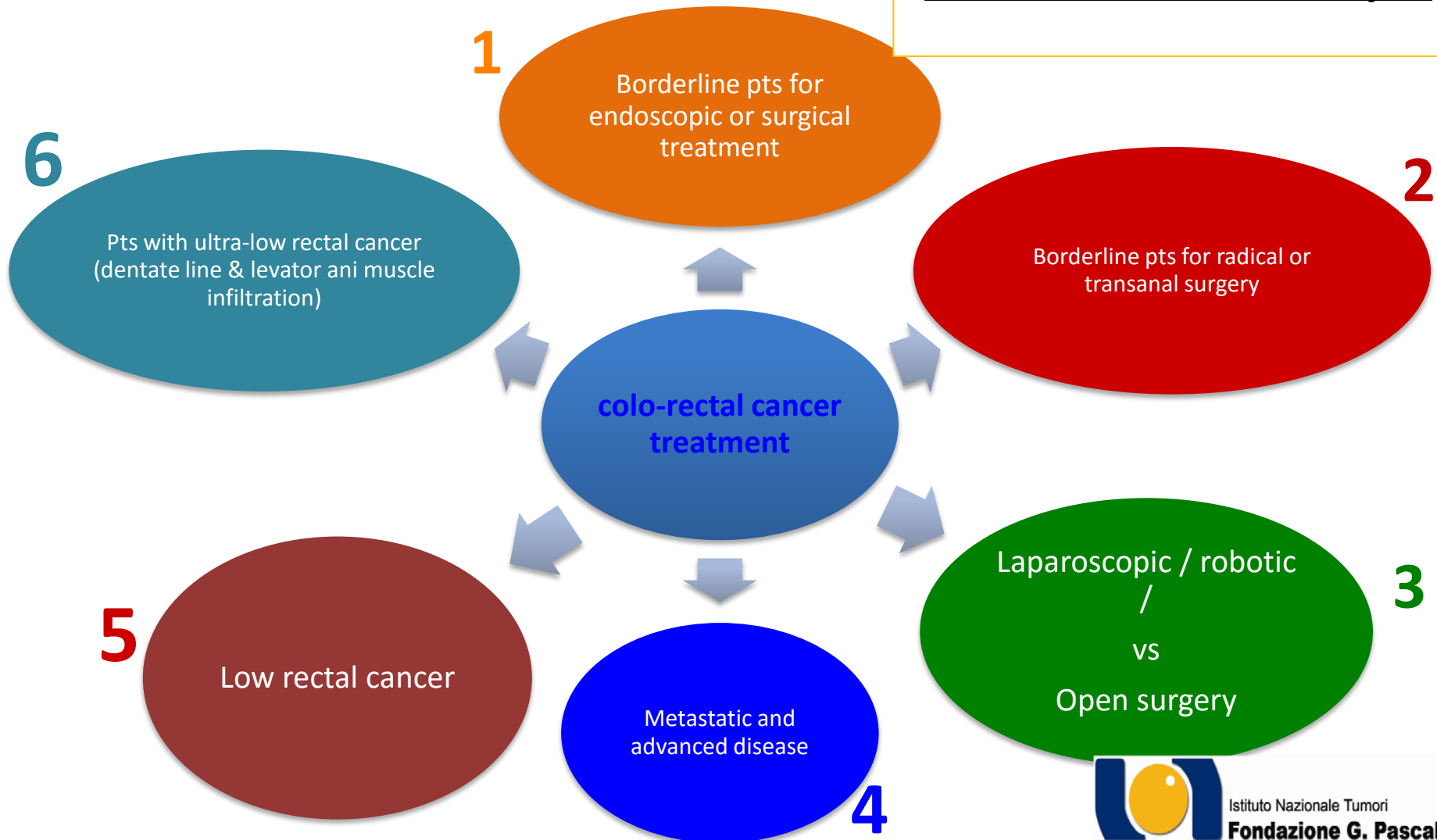
Regione Campania BURC n.37
del 13 Giugno 2016
Decreto n. 38 del 01.06.2016



Regione Campania
Il Commissario ad Acta

**OGGETTO: Programma Regionale per l'attuazione
delle misure sanitarie disposte dalla L.n.6 del 6
Febbraio 2014**

Esperienza di Best Practice sul
Carcinoma del colon-retto individuata a livello regionale



Istituto Nazionale Tumori
Fondazione G. Pascale

Low rectal cancer: sphincter saving or stoma?

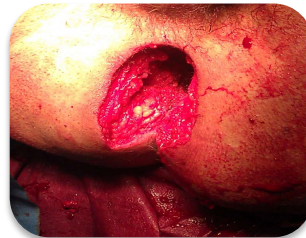


Opzioni terapeutiche:

Measures:

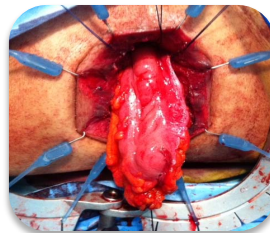
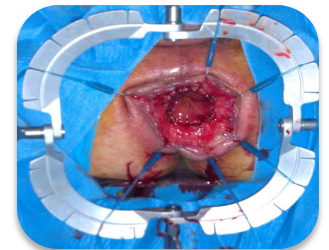


% sphincter saving
% stoma



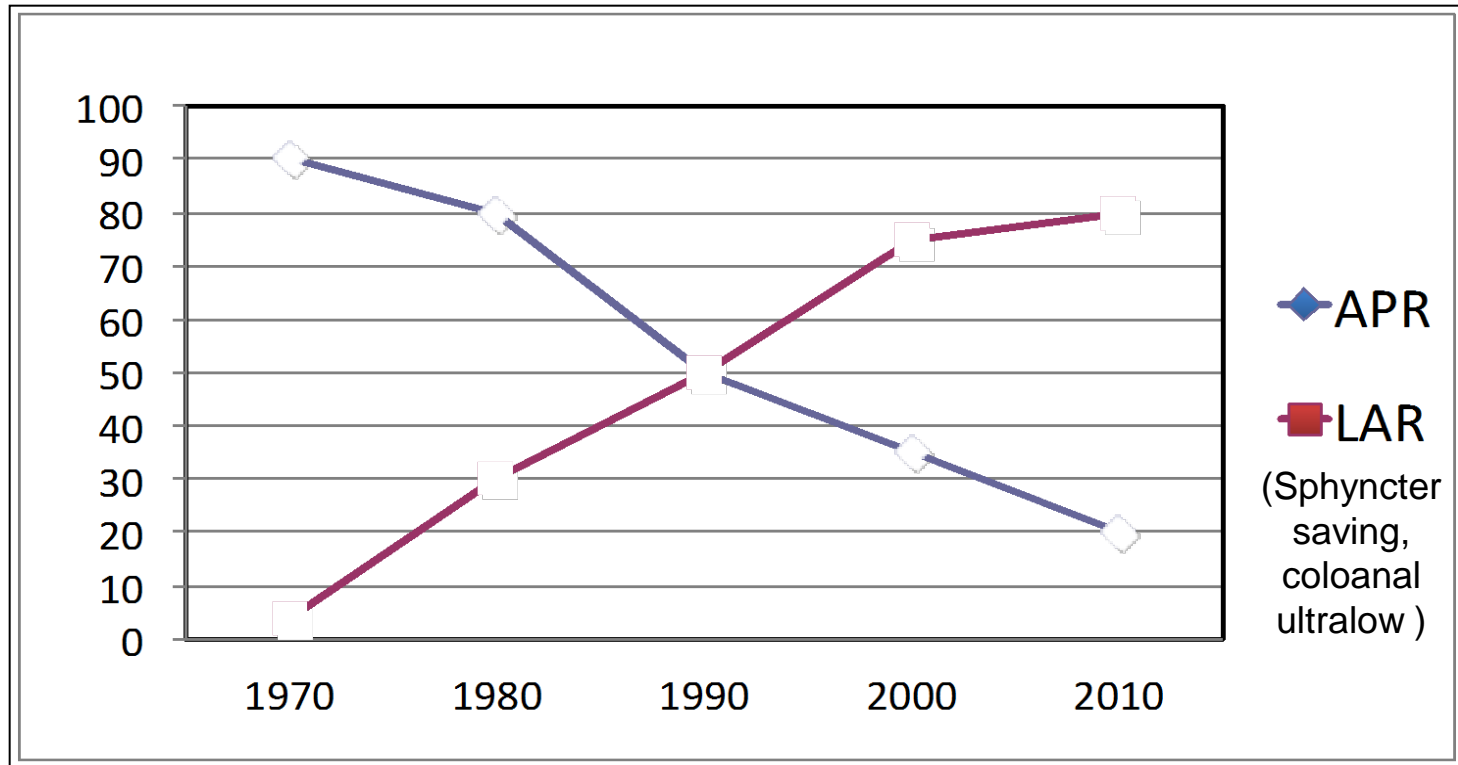
APR with definitive colostomy

**Coloanal anastomosis
with protective stoma**



Delayed coloanal anastomosis

The rate of APR did decrease during the last 15 years, while LAR is widely being used in the surgical treatment of rectal cancer.



Matsuoka H. Hepatogastroenterology. 2011 May-Jun;58(107-108):749-51.

Lim YK. World J Surg Oncol. 2010 Mar 26;8:23.

Mekras A. Tech Coloproctol. 2011 Ott

Mulsow J. World J Gastroenterol. 2011 Feb 21;17(7):855-61

Fischer A. Int J Colorectal Dis. 2010 Apr;25(4):425-32.

SSP vs APR

In the long run, the LAR/CAA offers patients good function with few side effects and is universally preferable to a permanent colostomy.

By avoiding permanent colostomy, cancer treatment is improved without compromising survival.

Paty PB, Enker WE. Hepatogastroenterology. 1992

Sphincter saving procedures does not compromise cure rate

261 patients, tumors 5-7cm from anal verge

Lavery IC et al. Surgery. 1997

| | SSP | APR | p |
|-------------------|-----|-----|------|
| N | 162 | 99 | |
| Loc. Rec. (%) | 8 | 11 | 0.4 |
| Distant mets (%) | 23 | 28 | 0.35 |
| Survival (5yr, %) | 71 | 63 | 0.2 |

Increasing SSP...

Surgeons should strive to perform rectal resection with sphincter preservation for low-lying rectal cancer whenever possible.

Tytherleigh MG, McC Mortensen NJ. *Br J Surg.* **2003**

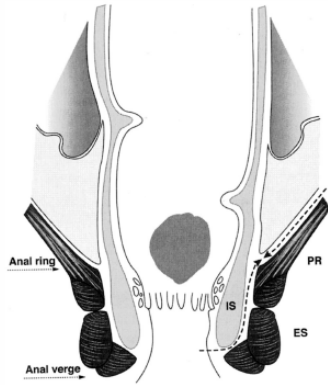
Classification of low rectal cancers and standardization of surgery permitted sphincter-preserving surgery in 79% of patients with low rectal cancer without compromising oncologic outcome.

This new surgical classification should be used to standardize surgery and increase sphincter-preserving surgery in low rectal cancer.

Rullier E. et al. *Dis Colon Rectum.* **2013**

Sphincter-Saving Resection for All Rectal Carcinomas
The End of the 2-cm Distal Rule

Eric Rullier, MD,* Christophe Laurent, MD,* Frédéric Bretagnol, MD,* Anne Rullier, MD,†
Véronique Vendrely, MD,‡ and Frank Zerbib MD, PhD§



Dis Colon Rectum. 2013 May;56(5):560-7.
Low rectal cancer: classification and standardization of surgery.

Rullier E, Denost Q, Vendrely V, Rullier A, Laurent C.

CLASSIFICATION

- Type I:** supra-anal tumors: >1 cm a.r.
- Type II:** juxta-anal tumors: <1 cm a.r.
- Type III:** intra-anal tumors: internal sphincter inv
- Type IV:** transanal tumors: external sphincter inv

- **COLOANAL AN.**
- **PARTIAL INTERSPH R.**
- **TOTAL INTERSPH R.**
- **APR**

A pull-through delayed "high" coloanal anastomosis: new tricks to refresh an old procedure

F. Bianco, S. De Franciscis, A. Belli,
V. Ragone & G. M. Romano

Techniques in Coloproctology
Official Journal of SICCR, MSCP, ISCRS,
ECTA, Colorectal Anal Group of Surgical
Section of Chinese Medical Association,
MSFPD

ISSN 1123-6337
Tech Coloproctol
DOI 10.1007/s10151-015-1273-x



Springer



Fig. 1 Macrotomy and upper edge of internal sphincter. First stage: level of stitches at cartilaginous points. Second stage: level of colonic stump cutting line



Fig. 2 Detachment of adhesions following stitches' tails up to the knots-markers and colonic stump sectioning



Fig. 3 Delayed "high" coloanal anastomosis

Coloanal anastomosis or abdominoperineal resection for very low rectal cancer: what will benefit, the surgeon's pride or the patient's quality of life?

Rosa Digennaro • Mirna Tondo • Filippa Cuccia •
Ivana Giannini • Francesco Pezzolla • Marcella Rinaldi •
Dario Scala • Giovanni Romano • Donato F. Altomare

Multicenter retrospective study

Karnofsky scale, EORTC-C30, EORTC-CR38, SF-36, PGWBI, ICIQ-SF, Stoma-QoL, AMS, FIQL, PAC-QoL Wexner's score and (ODS) score

Long-term QoL of cancer-free patients with permanent stoma after APR is equivalent to those treated by sphincter-saving straight CAA for low rectal cancer

and that ***the choice of the type of surgery should consider not only the surgeon's preference but also the consensus of the patient about the functional outcome of both procedures.***

Morbidity risk factors after low anterior resection with total mesorectal excision and coloanal anastomosis: a retrospective series of 483 patients.

Bennis M, Parc Y, Lefevre JH, Chafai N, Attal E, Tiret E.

164 (33.9%) suffered at least 1 complication, leading to death in 2 (0.4%) patients.

Grade III/IV complications occurred in 69 (14.2%) patients

34 (7.0%) patients developed leakage of the CAA

3 patients had leakage of the small bowel anastomosis after stoma closure.

Ileostomy closure was carried out after a mean of 88.7 days (36-630) after LAR.

The stoma was not closed in 4 of 456 (0.6%) patients.

Medical complications were associated with:

- previous thrombembolic events (P = 0.0012)
- associated surgery at the time of LAR (P = 0.0010)
- circumferential tumor localization (P = 0.0015)
- postoperative transfusion (P = 0.0025)

The only factor associated with a risk of leakage was transfusion (P = 0.0216).

Morbidity related to defunctioning ileostomy closure after ileal pouch-anal anastomosis and low colonic anastomosis.

van Westreenen HL, Visser A, Tanis PJ, Bemelman WA.

138 retrospectively analyzed after stoma reversal.

Overall complication rate: 20.3%.

Anastomotic leakage rate: 4.3%

Reoperation rate: 8.0%

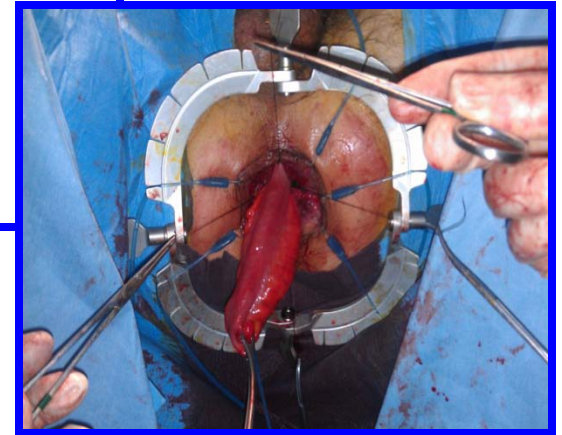
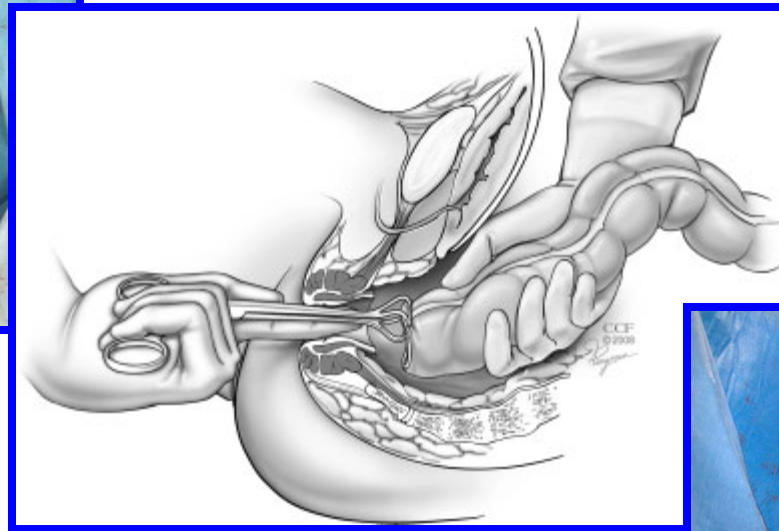
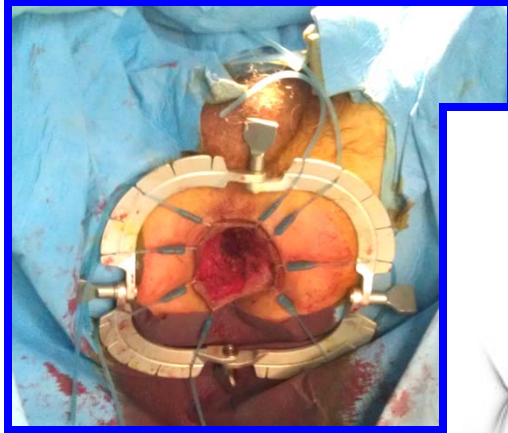
| Clavien-Dindo classification | N° of complication |
|------------------------------|--------------------|
| GRADE I | 5 (10.9 %) |
| GRADE II | 26 (56.5%) |
| GRADE III | 13 (28.3%) |
| GRADE IV | 1 (2.2%) |
| GRADE V | 1 (2.2%) |

Multivariate analysis revealed a significantly higher ASA score in the complicated group (P = 0.015, odds ratio 2.6, 95% confidence interval 1.2-5.6).

Closure of a defunctioning ileostomy is associated with 20% morbidity and a reoperation rate of 8%.

There is an urgent need for criteria on which a more selective use of a defunctioning ileostomy after low colonic anastomosis or IPAA can be based given its associated morbidity.

How to lessen complications in CAA?



Pullthrough procedure

Delayed colo-anal anastomosis is an alternative to prophylactic diverting stoma after total mesorectal excision for middle and low rectal carcinomas

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^aInstitut Bergonié, Université de Bordeaux, Institut Bergonié Unit, 229 cours de l'Argonne, 33076 Bordeaux Cedex, France

^bHôpital Albert Michallon, Université de Grenoble, Colorectal Unit, BP 217, 38043 Grenoble Cedex 9, France

^cInstitut Bergonié, Clinical Research and Clinical Epidemiology Unit, 229 cours de l'Argonne, 33076 Bordeaux Cedex, France

Accepted 6 December 2010

Available online 24 December 2010

Table 2
Surgical morbidity (according to the classification of Dindo et al.¹⁴).

| | |
|---|-----------|
| Anastomotic fistula (IIIb) | 2 |
| Rectovaginal fistula (IIIb) | 1 |
| Perianastomotic abscess (IIIa) | 6 |
| Pelvic haematoma (IIIb) | 1 |
| Colonic ischemia (IIIb) | 4 |
| Colonic perforation (IIIb) | 2 |
| Occlusion (IIIb) | 1 |
| Evisceration (IIIb) | 1 |
| Necrosis of the exteriorised colonic segment (IIIa) | 2 |
| Prostatic bleeding (IIIb) | 1 |
| Perianal abscess (IIIa) | 1 |
| Total | 22 |

Table 3
Morbidity in direct colo-anal anastomosis studies.

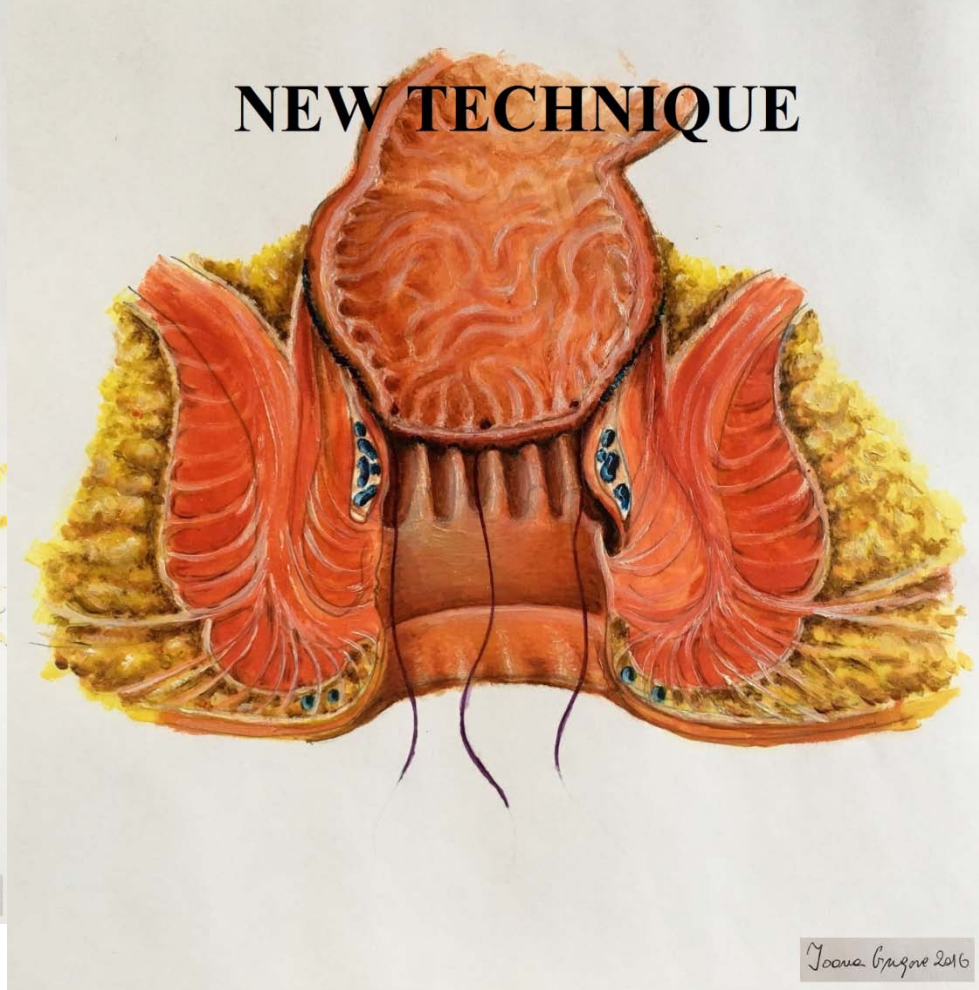
| Authors | Preventive diverting stoma | Anastomotic leak (%) | Pelvic abscess (%) |
|---------------------------------|----------------------------|----------------------|--------------------|
| Baulieux et al ¹¹ | 100% | 7.9 | 10.5 |
| Lazorthes et al ²² | 100% | 4.6 | 4.6 |
| Hautefeuille et al ² | 100% | 20 | – |
| Benchimol et al ²³ | 100% | 8.5 | – |
| Berger et al ²⁴ | 100% | 3 | 1.23 |
| Rullier et al ²⁵ | 100% | 10 | 3 |
| Our series of ACAD | 0% | 3 | 6 |

How we perform Pullthrough Procedure

OLD TECHNIQUE



NEW TECHNIQUE



Joana Braga 2016

Joana Braga 2016

Personal series: Surgical Details

| ID N. | SURGICAL TECH | DISTANCE FROM ANAL VERGE (cm) | STAGE (AJCC vers.7) | 30 DAYS COMPL sec.DINDO | PROCEDURE FAILURE |
|-------|---------------|-------------------------------|--------------------------------|-------------------------|-------------------|
| PT1 | OPEN | 4 CM | ypT2 ypN0 ypV0 ypR0 G2 | N | N |
| PT2 | OPEN | 4 CM | ypT1 ypN0 ypV0 ypR0 G2 , TRG 3 | IIIA | N |
| PT3 | OPEN | 4 CM | ypT0 ypN0 ypRo TRG 1 | N | N |
| PT4 | OPEN | 5 CM | pT2 pNx pV0 pR0 G2 | N | N |
| PT5 | OPEN | 3 CM | ypT3 ypN1a ypV0 ypR0 G2 | N | N |
| PT6 | OPEN | 5 CM | ypT2 ypN0 ypV0 ypR0 G2 TRG 3 | N | N |
| PT7 | ROBOTIC | 5CM | ypTis ypN0 ypV0 ypR0 G2 TRG 1 | N | N |
| PT8 | ROBOTIC | 6 CM | pT2 pN0 pV0 pR0 G2 | N | N |
| PT9 | OPEN | 5 CM | pT3 pN0 pV0 pR0 G2 | N | N |
| PT10 | OPEN | 5 CM | ypT2 ypN0 ypV0 ypR0 G2 TRG 2 | N | N |
| PT11 | OPEN | 2 CM | pTis pN0 pV0 pR0 G2 | N | N |
| PT12 | OPEN | 5 CM | ypT2 ypN0 ypV1 ypR0 G2 | N | N |
| PT13 | OPEN | 5 CM | ypT1 pN0 pV0 pR0 G2 | N | N |
| PT14 | OPEN | 4 CM | ypT2 ypN1b ypV0 ypR0 G2 TRG 2 | N | N |
| PT15 | VLS | 4 CM | ypT1 pN0 pV0 pR0 G2 | I | N |
| PT16 | OPEN | 5CM | ypT3 ypN0 ypV0 ypR0 G2 TRG 3 | N | N |
| PT17 | VLS | 6 CM | ypT2 ypN0 ypV0 ypR0 G2 | N | N |
| PT18 | OPEN | 6 CM | pT1 pN0 pV0 pR0 G2 | N | N |
| PT19 | VLS | 3 CM | ypT1 ypN0 ypV0 ypR0 G2 TRG2 | N | N |
| PT20 | VLS | 3 CM | ypT1 YpN0 pV0 pR0 G2 TRG2 | N | N |
| PT21 | VLS | 3CM | pTis pN0 pV0 pR0 G2 | N | N |
| PT22 | VLS | 6 CM | ypT2 ypN0 ypV0 ypR0 G2 TRG 3 | N | N |
| PT23 | OPEN | 3 CM | ypT2 ypN0 ypV0 ypR0 G2 TRG 2 | N | N |
| PT24 | OPEN | 5 CM | ypTis ypN0 ypV0 ypR0 G2 TRG 1 | N | N |
| PT25 | OPEN | 3 CM | ypT2 ypN0 V0 R0 G2 TRG2 | I | N |

- **First step**
m.v. 280 min
- **Robotic procedure**
m.v. 480 min
- **Second step**
m.v. 36 min
- **Hospital stay**
12 days
- **Median follow up**
24 months
(range 6- 60)

Personal series: Results

-25 PT procedure (2011-2016) for ultralow rectal cancer

- ✓ Stump ischemia: 0%
- ✓ Stump retraction: 0%
- ✓ Major Anastomosis leakage: 0%
- ✓ Technical failure: 0%
- ✓ Substenosis (asympt-endoscopic treat): 8% (2pz)
- ✓ 30 day major morbidity: 4% (1pz)
- ✓ 30 day minor morbidity: 8% (2 pz)
- ✓ Post- op Mortality: 0%
- ✓ Follow-up (asympt-coservative treat): 32% (9pz)

Personal series: Functional Results

| ID N. | FOLLOW-UP | | | | | | | | | | | | | | LARS Syndr | | | | |
|-------|-----------|------|-----|------|-----|------|------|------|------|------|------|------|------|------|------------|------|------|------|------------|
| | PREOP | | 3 M | | 6 M | | 12 M | | 18 M | | 24 M | | 36 M | | | 48 M | | 60 M | |
| | WEX | LARS | WEX | LARS | WEX | LARS | WEX | LARS | WEX | LARS | WEX | LARS | WEX | LARS | | WEX | LARS | WEX | LARS |
| PT1 | 0 | 0 | | | | | | | | | | | | | | | 12 | 23 | Minor LARS |
| PT2 | 0 | 0 | | | | | | | | | | | | | 6 | 21 | | | Minor LARS |
| PT3 | 0 | 0 | | | | | | | | | | | | | 12 | 29 | | | Minor LARS |
| PT4 | 0 | 0 | | | | | | | | | | | | | 19 | 23 | | | Minor LARS |
| PT5 | 0 | 0 | | | | | | | | | | | 11 | 37 | | | | | Major LARS |
| PT6 | 0 | 0 | | | | | | | | | | | 14 | 39 | | | | | Major LARS |
| PT7 | 0 | 0 | | | | | | | | | | | 13 | 19 | | | | | No LARS |
| PT8 | 0 | 0 | | | | | | | | | | | 7 | 18 | | | | | No LARS |
| PT9 | 9 | 14 | | | | | | | | | | | 16 | 41 | | | | | Major LARS |
| PT10 | 0 | 0 | | | | | | | | | | | 15 | 20 | | | | | No LARS |
| PT11 | 0 | 0 | | | | | | | | 12 | 25 | | | | | | | | Minor LARS |
| PT12 | 0 | 0 | | | | | | | | 4 | 21 | | | | | | | | Minor LARS |
| PT13 | 0 | 0 | | | | | | | | 1 | 9 | | | | | | | | No LARS |
| PT14 | 0 | 0 | | | | | | | | 16 | 34 | | | | | | | | Major LARS |
| PT15 | 0 | 0 | | | | | | | | 3 | 12 | | | | | | | | No LARS |
| PT16 | 0 | 0 | | | | | | | | 1 | 3 | | | | | | | | No LARS |
| PT17 | 0 | 14 | | | | | | | | 2 | 24 | | | | | | | | Minor LARS |
| PT18 | 0 | 0 | | | | | | | | 4 | 31 | | | | | | | | Major LARS |
| PT19 | 0 | 0 | | | | | | | 11 | 29 | | | | | | | | | Minor LARS |
| PT20 | 0 | 0 | | | | | | | 2 | 28 | | | | | | | | | Minor LARS |
| PT21 | 0 | 0 | | | | | 6 | 32 | | | | | | | | | | | Major LARS |
| PT22 | 0 | 0 | | | | | 12 | 37 | | | | | | | | | | | Major LARS |
| PT23 | 0 | 0 | | | | | 7 | 34 | | | | | | | | | | | Major LARS |
| PT24 | 0 | 0 | | | | | 8 | 39 | | | | | | | | | | | Major LARS |
| PT25 | 0 | 0 | | | 9 | 37 | | | | | | | | | | | | | Major LARS |

**Median follow up
24 months
(range 6- 60)**

Interpretation:

| | |
|------------|-----|
| Major LARS | 40% |
| Minor LARS | 36% |
| No LARS | 24% |

| Interpretation: | |
|-----------------|-------|
| No LARS | 0-20 |
| Minor LARS | 21-29 |
| Major LARS | 30-42 |

**Prospective Multicenter Randomized Controlled Trial
On Two-Stage Turnbull-Cutait Coloanal Anastomosis
For Rectal (TURNBULL-BCN)**

Sebastiano Biondo, Hospital Universitari de Bellvitge

**The aim of this study is to decrease the morbidity by 30%
using the Turnbull-Cutait procedure in comparison to the
standard surgery for low rectal cancer.**

The investigators compare quality of life, faecal incontinence and recurrence of neoplasm in patients who received standard colo-anal anastomosis with protective ileostomy or two-staged Turnbull-Cutait colo-anal anastomosis after Low Anterior Resection for rectal cancer.

Pts with ultra-low rectal cancer (levator ani muscle infiltration) APR o ELAPE?



Standard APR



MULTICENTER RANDOMIZED CONTROLLED TRIAL, EXTRALEVATOR VS. STANDARD ABDOMINOPERINEAL RESECTION FOR RECTAL ADENOCARCINOMA



[Colorectal Dis.](#) 2016 Jul 1. doi: 10.1111/codi.13436. [Epub ahead of print]

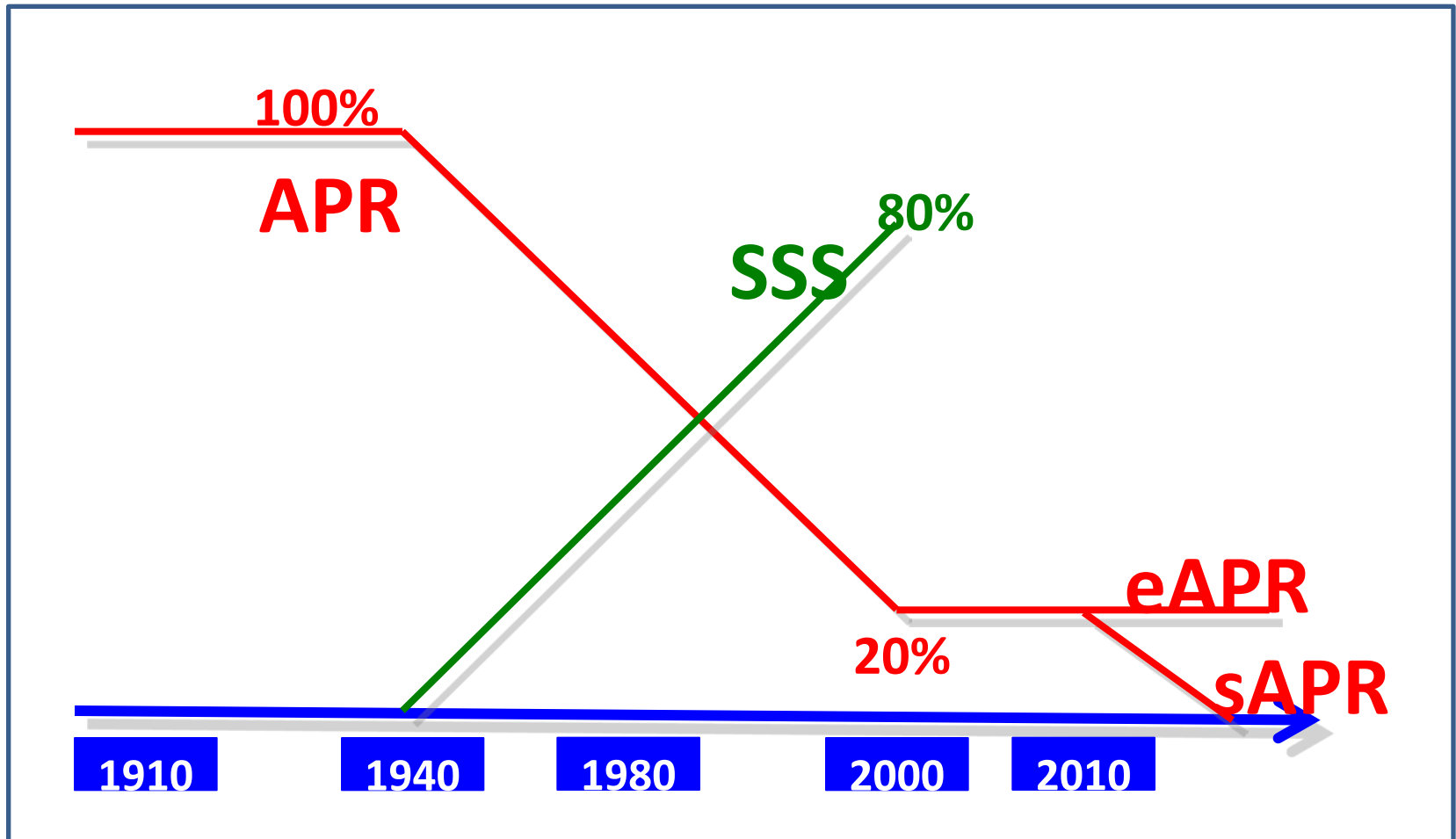
Extralevator with vertical rectus abdominis myocutaneous flap vs. non-extralevator abdominoperineal excision for rectal cancer: the RELAPe randomized controlled trial.

[Bianco F^{1,2}](#), [Romano G²](#), [Tsarkov P³](#), [Stanojevic G⁴](#), [Shroyer K⁵](#), [Giuratrabocchetta S¹](#), [Bergamaschi R¹](#); [International Rectal Cancer Study Group](#).



Cylindrical APR

The rate of APR did decrease during the last 100 years, while SSS is widely being used in the surgical treatment of rectal cancer.



WHEN AN APR IS INDICATED?

- Low rectal cancer T3-T4 (MRI e/o endorectal ultrasound)**
- Breach of external sphincter & levator m**
- Rectal cancer and incontinent Sphincter**

- Advanced anal cancer (Salvage surgery)**

DOES NEOADJUVANT THERAPY



INCREASE SPHYNCTER SAVING PROCEDURES?

[Radiother Oncol.](#) 2004 Jul;72(1):15-24.

Sphincter preservation following preoperative radiotherapy for rectal cancer: report of a randomised trial comparing short-term radiotherapy vs. conventionally fractionated radiochemotherapy.

Bujko K, Nowacki MP, et al.

Sauer R, Becker H, et al.; German Rectal Cancer Study Group.

Preoperative versus postoperative chemoradiotherapy for rectal cancer.

N Engl J Med. 2004 Oct 21;351(17):1731-40.

CONSENSUS CONFERENCE on EARLY RECTAL CANCER EAES Paris 2014

Indication for APR in early rectal cancer:

NONE +++

Choice between:

- Partial or subtotal resection of internal anal sphincter
- Low/ultralow anterior resection

EAES Paris 2014

APR post - Neoadjuvant therapy ?



Pro APR

**DECISION
LARGELY BASED
ON PATIENT OR
SURGEON PREFERENCE**

**Pro sphincter
saving**

Standard abdominoperineal resection: more LR, less OS.

The Dutch Trial:

CRM involvement:

26.5% for lower cancer
undergoing APR

12,6% for higher cancer
undergoing LAR

Perforation:

13,7% for APR
2,5% for LAR

**Lower cancer undergoing APR have
more LR and less OS**



Standard
APR

Nagtegaal ID, van de Velde CJ, Marijnen CA, van Krieken JH, Quirke P; Dutch Colorectal Cancer Group; Pathology Review Committee.

Low rectal cancer: a call for a change of approach in abdominoperineal resection.

J Clin Oncol. 2005 Dec 20;23(36):9257-64.

APR or ELAPE, Which is better?

Extended techniques of APE result in superior oncologic outcome as compared to standard techniques

[Br J Surg.](#) 2010 Apr;97(4):588-99.
Multicentre experience with extralevator abdominoperineal excision for low rectal cancer.

[West NP](#), [Anderin C](#), [Smith KJ](#), [Holm T](#),
[Quirke P](#); [European Extralevator Abdominoperineal Excision Study Group](#).

[Int J Colorectal Dis.](#) 2011 Oct;26(10):1227-40.
Extended abdominoperineal excision vs. standard abdominoperineal excision in rectal cancer--a systematic overview.
[Stelzner S](#), [Koehler C](#), [Stelzer J](#), [Sims A](#),
[Witzigmann H](#).

Extralevator APE is associated with less CRM involvement and IOP than standard surgery

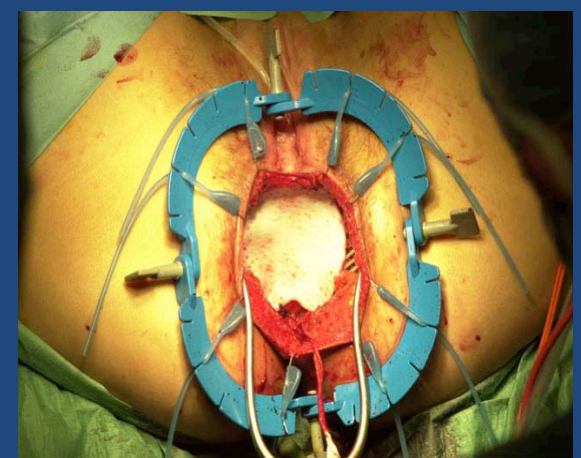
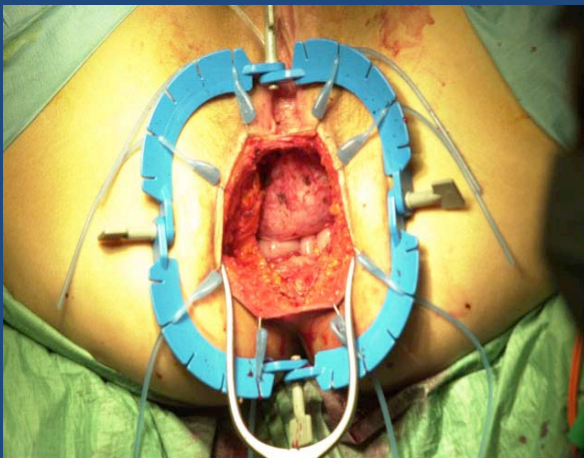
...SEEM TO CONFIRM...NEVERTHELESS...

Systematic review and meta-analyses

| | Negoi 2016 | Yang 2015 | De Nardi 2015 | Yu 2014 | Huang 2014 | Stelzner 2011 |
|----------------------------|---------------|--------------|------------------|-------------|---------------|------------------|
| Operation time | | | | NS | | |
| Blood loss | eAPR | | | NS | | |
| Complications overall | | | | NS | | |
| Wound complications | | NS | sAPR | NS | | NS |
| Intraop perforation | eAPR | eAPR | eAPR | eAPR | eAPR | eAPR |
| CRM (+) | NS | NS | | eAPR | eAPR | eAPR |
| LR | NS | eAPR | eAPR | eAPR | eAPR | eAPR |
| OS | | | | - | | |



DO WE REALLY NEED AN EXTENDED APR IN THE NEOADJUVANT ERA?



National data

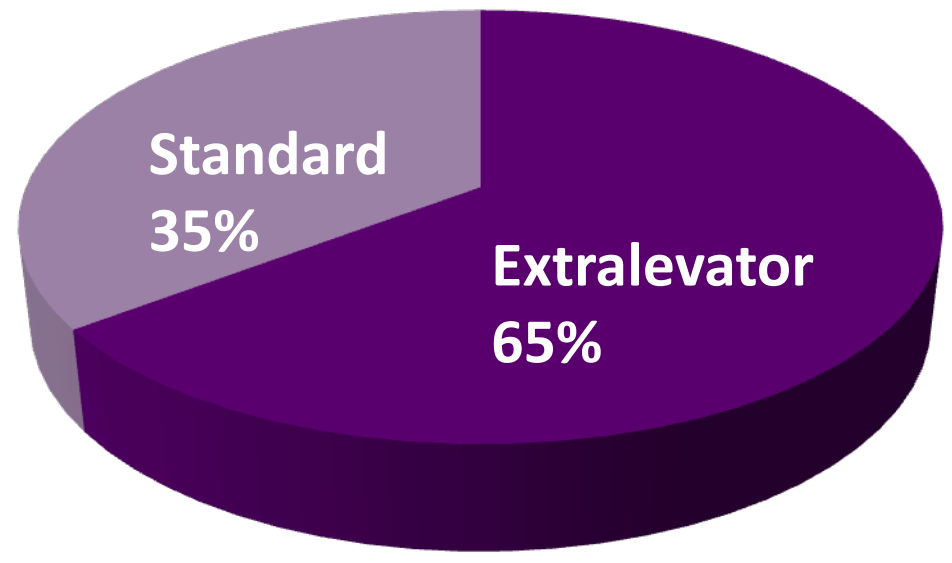
Jones Colorectal Dis 2016

UK - LOREC

2012-2014

42 units

266 pts



National data

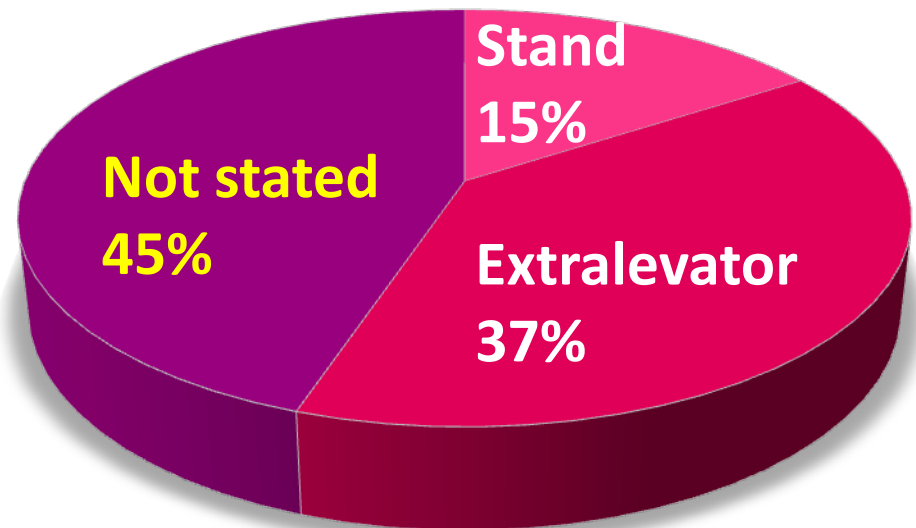
Prytz et al. Int J Colorectal Dis 2014

Prytz et al. Ann Surg 2015

Sweden – Colorectal cancer registry

2007-2009

1397 pts



National data

Prytz et al. Int J Colorectal Dis 2014

Prytz et al. Ann Surg 2015

Sweden – Colorectal cancer registry

2007-2009

1397 pts



CONCLUSIONS

We believe, on the basis of the results from this study and supported by the results from Ortiz et al, that ELAPE should not be suggested as a standard operative technique for all low rectal cancers. On the basis of our results, we suggest that ELAPE should be used with discretion, primarily for cases with high risk of intraoperative perforation—which in our study seems as a major risk factor for local recurrence.

Swedish Registry data - Recall bias

Bianco, Romano, Tsarkov, Tulina, Bergamaschi
Ann Surg – epub ahead of print (2016)

A Giant With Clay Feet

To the Editor:

The article by Prytz et al¹ addresses a controversial topic in the colorectal surgery literature—namely, abdominoperineal procedures for rectal cancer. Interestingly, the study¹ refers to the same cohorts of patients analyzed within the same time frame in a previous publication.²

There are at least three categories for discussion: (i) recall bias to determine type of abdominoperineal procedure performed; (ii) questionable indications for abdominoperineal procedures in patients with tumors not involving the sphincters; and (iii) conflicting data in publications addressing the same cohorts of patients.^{1,2}

The first point of discussion refers to the authors' breakdown of the series into groups based on their perception of what

noncomparability of the study arms. The second concern refers to the inclusion in the analysis of patients with a rectal cancer located more than 4 cm from the anal verge.¹ Abdominoperineal procedures should be indicated for patients with a suspected involvement of the sphincter muscles. In fact, procedures such as intersphincteric resections may be considered as an option in case of absence of sphincter involvement. Moreover, Prytz et al¹ failed to provide the readers with the T-stage stratification of the subgroup of patients with cancer located less than 4 cm from the anal verge to prove comparability. The third category for discussion involves a back-to-back comparison of publications.^{1,2} In the recent article,¹ ELAPE resulted in a significantly increased 3-year local recurrence rate as compared with non-ELAPE with intraoperative perforation as an important risk factor for local recurrence. In

3.0 cm for non-ELAPE and ELAPE, respectively ($P < 0.0001$).¹ Table 1 of the previous publication² showed 17 patients (8%) versus 176 patients (34%) with tumor location less than 2 cm from the anal verge in the non-ELAPE and ELAPE arms, respectively (P value not reported). Furthermore, the long-course radiation ratio (non-ELAPE 24% vs ELAPE 36%, $P < 0.0001$) represents an additional bias.

In conclusion, the readers should be less impressed with the size of the series and more attentive to the quality of the methodology.

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Photography. 2011

MULTICENTER RANDOMIZED CONTROLLED TRIAL, EXTRALEVATOR VS. STANDARD ABDOMINOPERINEAL RESECTION FOR RECTAL ADENOCARCINOMA Study

Original article

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Extralevator with vs nonextralevator abdominoperineal excision for rectal cancer: the RELAPe randomized controlled trial

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**MULTICENTER RANDOMIZED CONTROLLED TRIAL,
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Randomization will be computer generated

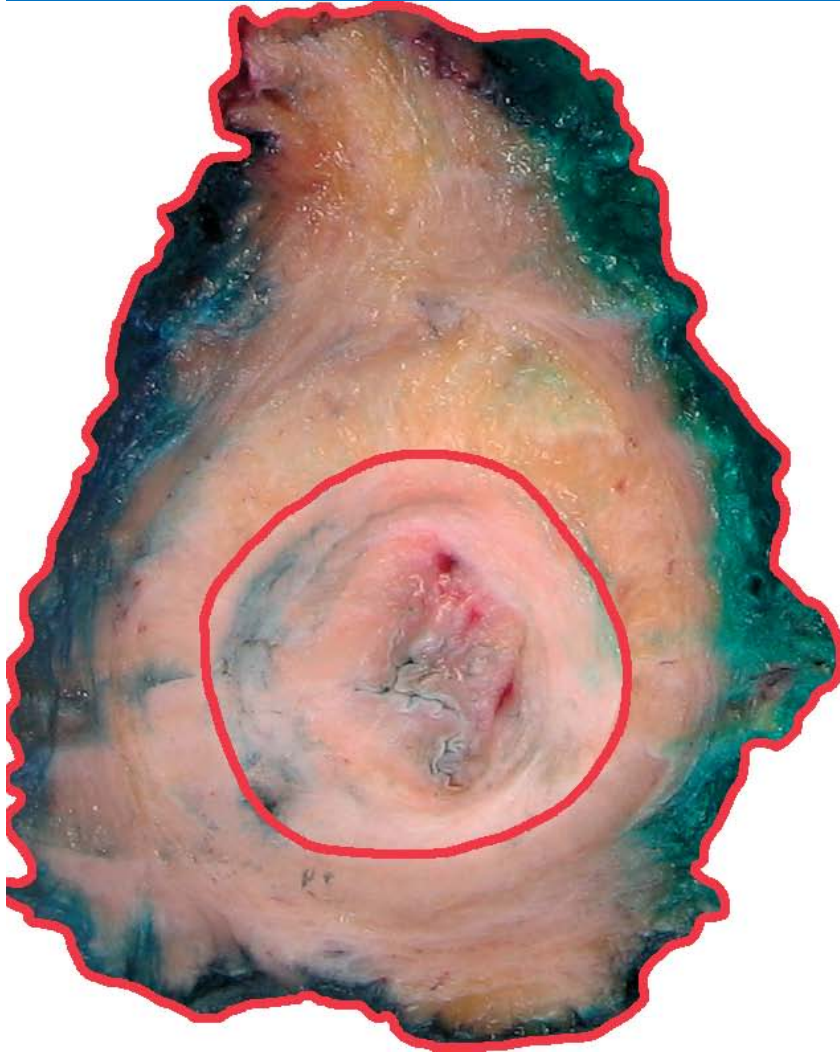
Patients will be randomized only after completion of neoadjuvant chemoradiation.



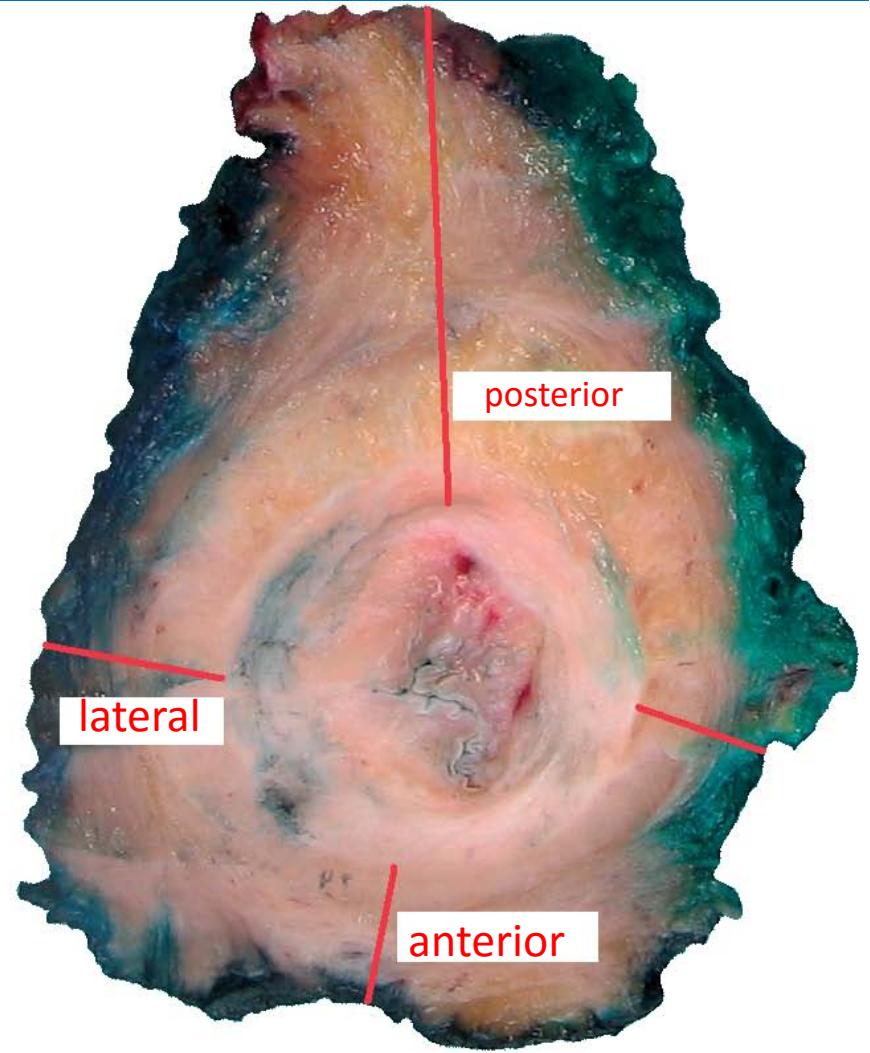
APR

ELAPE

TISSUE MORPHOMETRY MEASUREMENT TECHNIQUE



Area of tissue removed



Linear distance

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Table 5 Postoperative complications.

| Variable | ELAPE (n = 17) | Non-ELAPE (n = 17) | P |
|---------------------------------|----------------|--------------------|------|
| Intra-operative prostate injury | 1 (5.8%) | 0 (0%) | 0.77 |
| Complications* | 9 (5 pts) | 9 (6 pts) | 0.97 |
| Surgical site infections | 2 (22%) | 1 (11%) | 0.38 |
| Organ space | 0 | 1 (14%) | |
| Perineal wound | 2 (29%)†† | 0 | |
| Bleeding | 1 (11%)‡ | 1 (11%)† | 0.89 |
| Stoma complications | 0 | 0 | 1 |
| Postoperative ileus | 1 (11%)‡ | 0 | 0.63 |
| Urinary retention | 2 (22%)††,‡‡ | 2 (22%)§¶ | 0.59 |
| Urinary tract infection | 2 (29%)††,‡‡ | 2 (29%)†§§ | 0.53 |
| Deep venous thrombosis | 0 | 2 (29%)§¶ | 0.46 |
| Myocardial infarction | 0 | 1 (14%)** | 1 |
| Pneumonia | 1 (14%) | 0 | 1 |
| Clavien–Dindo Grade* | | | |
| I | 3 | 0 | 0.15 |
| II | 3 | 4 | |
| IIIa | 0 | 0 | |
| IIIb | 2 | 1 | |
| IVa | 0 | 1 | |
| IVb | 0 | 1 | |
| V | 0 | 2 | |
| Reoperation | 1‡ | 1† | 1 |
| Readmission | 0 | 2 (11%)§§∞ | 0.46 |
| Death | 0 | 2 (11%)§§** | 0.46 |

Table 6 Pathology data.

| Variable | ELAPE (n = 17) | Non-ELAPE (n = 17) | P |
|------------------------------------|----------------|--------------------|-------|
| pT staging | | | |
| pT0 | 1 (5.9) | 2 (11.8) | -1.0 |
| pT1 | 4 (23.5) | 3 (17.6) | 1.0 |
| pT2 | 7 (41.2) | 6 (35.3) | 1.0 |
| pT3 | 3 (17.6) | 5 (29.4) | 0.57 |
| pT4 | 2 (11.8) | 1 (5.9) | 1 |
| pN staging | | | |
| pN0 | 16 (94) | 12 (70.6) | 0.57 |
| pN1a | 0 | 1 (5.9) | 1.0 |
| pN1b | 0 | 3 (17.6) | 1.0 |
| pN2 | 1 (5.9) | 1 (5.9) | 1.0 |
| Specimen length (cm) | 38.4 ± 12 | 34 ± 8.21 | 0.21 |
| Tumour diameter (cm) | 2.92 ± 0.74 | 2.3 ± 1.72 | 0.22 |
| Proximal margin (cm) | 33.4 ± 12.6 | 24.31 ± 10 | 0.029 |
| TME quality | | | |
| Complete | 16 (94) | 12 (70) | 0.11 |
| Near complete | 1 (6) | 1 (5.8) | |
| Incomplete | 0 | 4 (24.2) | |
| Nodes harvested | 16.06 ± 6.27 | 12.17 ± 5.7 | 0.07 |
| Node metastasis | 0 | 0 (0–1) | 0.13 |
| CRM (mm) | 7.14 ± 5.76 | 2.98 ± 3.28 | 0.016 |
| CRM involvement | 1 (5.8) | 7 (41) | 0.04 |
| Intra-operative rectal perforation | 1 (5.8) | 2 (11) | 0.77 |

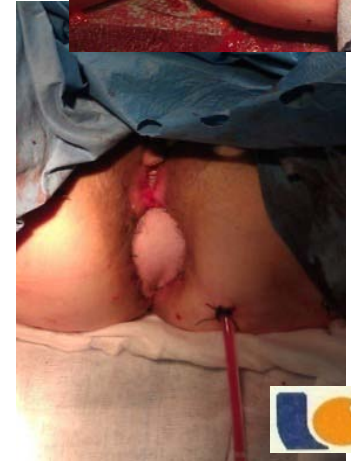
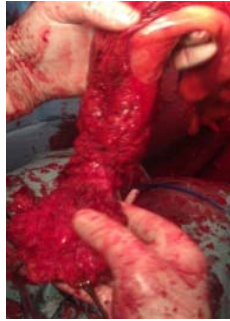
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Conclusions ELAPE was associated with statistically improved CRM with no difference in IOP and complication rates compared with non-ELAPE for rectal cancer involving the external anal sphincter.

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**APR or
SSR
???**

**Gluteus
or
VRAM
???**

**FLAP or
MESH?
??**

**STANDARD
or
EXTENDED
???**



**Which
mesh?
???**