

Laparoscopic, transanal, robotic or even open rectal resection: an agony of choice?

Prof. Markus von Flüe



19th century: Survive the surgery!



Image 2. Approach for Kraske's posterior proctectomy: Left wing of sacral bone hollowed with chisel and removed [4].

„Limited“ resection by mostly posterior approach

Analysis of 1500 cases before 1900
from Kocher, Billroth, Kraske, Czerny



Operative mortality 21%
Local recurrence 80%

20th century: Survive the cancer!



Image 3. Dr. William Ernest Miles [3]

Miles 1908: Report of 12 cases with **APR**
Mortality 42% (5)
Overall survival 1 year 58% (7)



Claude Dixon 1948 **Anterior resection**
6-20 cm from dentate line
Two stage procedure
Mortality 2.6%
5yrs-survival 64%



Sir Alan Parks 1970
Low anterior resection

20th century: Survive the cancer!



Bill Heald 1980: TME

Prior: blunt dissection with 25% lateral positive margins, 85% LRR

After: TME, CRM + 3.6%, **5 yrs LRR 4%, 5 yrs OS 80%**

21th century: Preserve the function!

- 1951 Goligher, Dukes, and Bussey: **distal margin 5 cm**
 - 1500 specimens, 2% spread distally >2cm
- 1953 Pollett and Nichols: **distal margin 2 cm**
 - 23 recurrences in 334 patients. No difference for distal margin <2cm, 2-5cm and >5cm
- 2003 Harvey Moore: **distal margin 1 cm or less**
 - After **neoadjuvant treatment** no difference <1cm and >1 cm

21th century: Minimize surgical trauma!

Laparoscopic rectal cancer surgery

ACS-NSQIP 2005-2016, USA

N=31'795

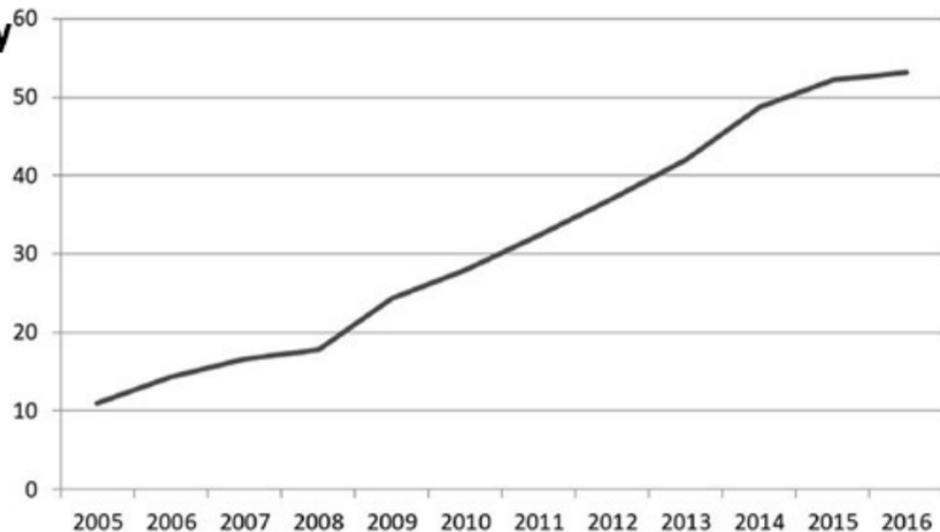
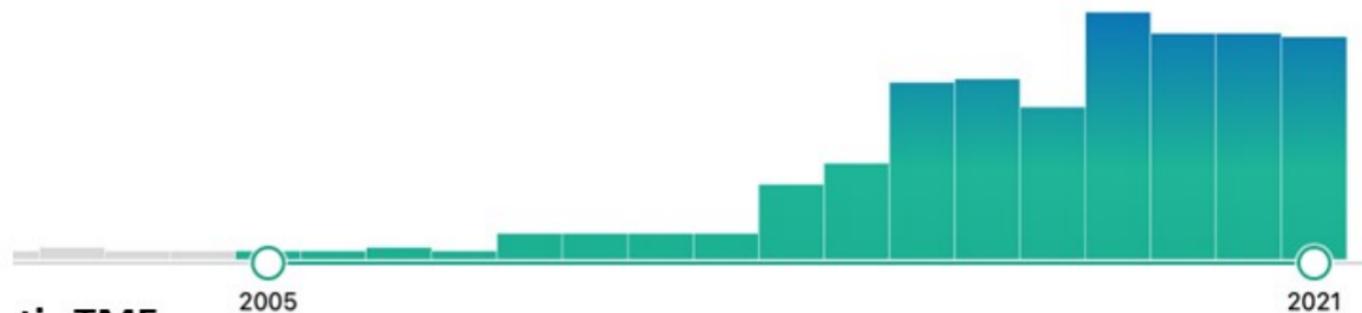


Fig. 1. Overall prevalence of laparoscopic resection for rectal cancer by year.

21th century: Minimize surgical trauma!

Publications on **taTME**

385 results



Publications on **Robotic TME**

RESULTS BY YEAR

210 results

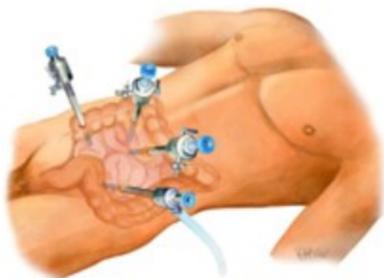


Agony of choices

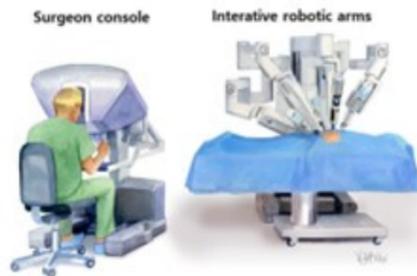
open



laparoscopic



robotic



ta-TME



Advantages of Laparoscopy

Laparoscopy vs open

(CLASSIC trial)

| | |
|--------------------------|---------|
| ↘ local complications | OR 0.51 |
| ↘ wound infections | OR 0.47 |
| ↘ time to gas | -33% |
| ↘ pain at rest, day 3 | -62.5% |
| ↘ opioid use (first 48h) | -36.9% |
| ↘ hospital stay | -20.6% |

Oncologic equivalent?



Colorectal cancer (lap. vs. open)

UK MRC CLASSIC (n=794)

- ✓ 3yrs disease free survival 66.3% vs 67.7%
- ✓ 3yrs local recurrence rate 8.6% vs 7.9%

COLOR (n=1248)

- ✓ 3yrs disease free survival 74.2% vs 76.2%

COST (n=872)

- ✓ 5yrs disease free survival 69.2% vs 68.4%

ALCCaS (n=601)

- ✓ 5yrs disease free survival 77.7% vs 76%

Guillou PJ, Lancet 2005; Veldkamp R, Lancet Oncol 2005; Jayne DG, Surg Oncol 2007, 25; Bonjer HJ, Lancet Oncol 2009; Fleshman J, Ann Surg 2007; Bagshaw PF, Ann Surg 2012; Abraham NS, Br J Surg 2004

...and for rectal cancer?



Subgroup rectal cancer

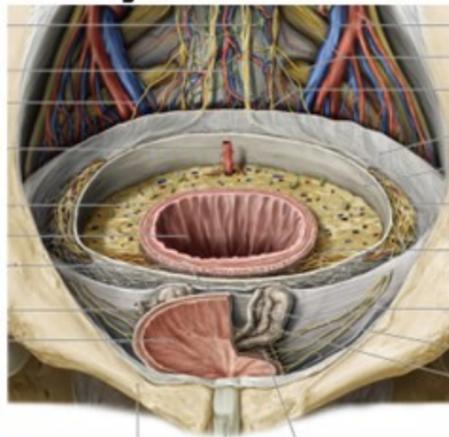
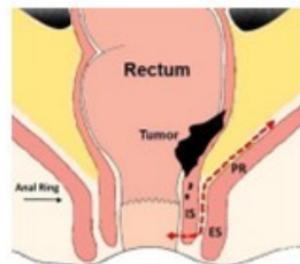
| | | |
|-----------------------|--------------|--------|
| CRM + | 12% vs 6% | p=0.19 |
| 3yrs local recurrence | 7.8% vs 7.0% | p=0.70 |

- COLOR II
- COREAN
- ALaCaRT
- ACOSOG Z6051

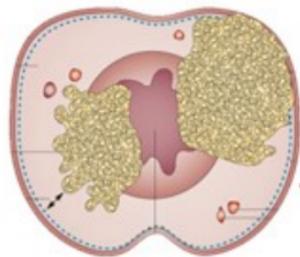
Guillou PJ, Lancet 2005; Veldkamp R, Lancet Oncol 2005; Jayne DG, Surg Oncol 2007, 25; Bonjer HJ, Lancet Oncol 2009; Fleshman J, Ann Surg 2007; Bagshaw PF, Ann Surg 2012; Abraham NS, Br J Surg 2004

Oncologic Quality of Rectal Cancer Surgery

Distal margin



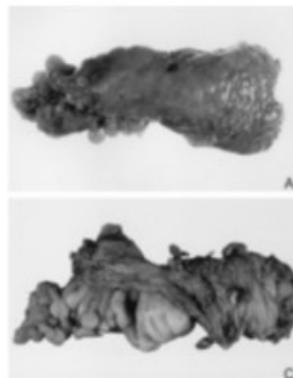
Circumferential margin (CRM)



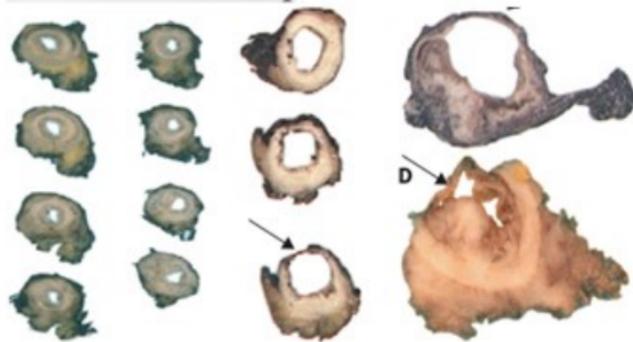
Survival Local Recurrence

| | Local recurrence | Distant metastases | Survival (2 y) | No. |
|--------------|------------------|--------------------|----------------|-----|
| ≤0.10 cm | 16.4% | 37.6% | 69.7% | 120 |
| 0.11–0.20 cm | 14.9% | 21.0% | 84.8% | 53 |
| 0.21–0.50 cm | 10.3% | 17.2% | 87.0% | 139 |
| 0.51–1.00 cm | 6.0% | 8.2% | 91.2% | 155 |
| >1.00 cm | 2.4% | 10.9% | 92.8% | 189 |
| | p = 0.0007 | p < 0.0001 | p < 0.0001 | |

Quality of specimen



2-yr recurrence:
 good/nearly tot 14.9%
 poor 28.6%
 p=0.03



ALaCaRT and ACOSOG Z6051

* non-inferiority

* non-inferiority

| Lap. vs. open | ALaCaRT (n=475) | ACOSOG Z6051 (n=486) |
|--------------------------------------|---|--------------------------------------|
| Non inferiority boundary | 8% | 6% |
| centers | 24 | 35 |
| surgeons | Video-Assessment ≥ 30 lap. Rektum / ≥ 100 lap. Kolon | Video-Assessment ≥ 20 lap. Rektum |
| Tumour stages | I-III | II-III (T3 N0-2) |
| Neoadjuvant chemoradiation | 49.5% | Alle |
| conversions | 9% | 11.3% |
| Combined endpoint, % (95%CI): | 82 vs. 89 (-12.4 to ∞) | 81.7 vs. 86.9 (-10.8 to ∞) |
| - Negative CRM (≥ 1mm) | <div style="border: 1px solid black; padding: 5px; text-align: center;"> Post-hoc test for superiority 95%CI -13.8;-0.6, p=0.03 </div> | |
| - Distal margin (≥ 1mm) | | |
| - Specimen good/nearly total | | |
| Specimen good/nearly tot, % (95%CI) | 97 vs. 99 (-10.9 to 0.2) | 92.1 vs. 95 (-7.4 to 1.5) |
| CRM free (>1mm), % (95%CI) | 93.3 vs. 97 (-7.6 to 0.1) | 87.9 vs. 92.3 (-9.8 to 0.98) |
| Distal margin (>1mm), % (95%CI) | 99 vs. 99 (-1.8 to 1.0) | 98.3 vs. 92.2 (-2.3 to 2.5) |

Stevenson ARL, JAMA Surgery 2015; Fleshman J, JAMA Surgery 2015

Meta-Analysis

| lap. vs open | Including | Endpoint | Result |
|-----------------------|------------------|-------------------------|-----------------------|
| ✘ Martinez-Perez 2017 | 14 RCT n=4034 | CRM+ | 7.9% vs 6.1%, p=0.26 |
| | | Specimen good | 86.8% vs 89.6% p=0.02 |
| ✔ Creavin 2017 | 4 RCT n=2319 | CRM+ | 7.5% vs 6.1% p=0.31 |
| | | Speciment good/near tot | 95.9% vs 96.5% p=0.26 |

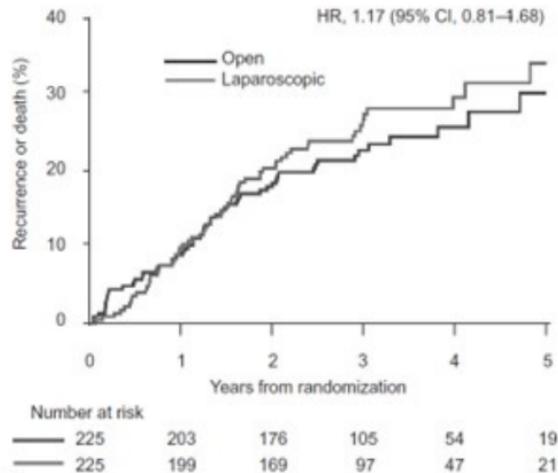
ALaCaRT

| Lap. vs. open | ALaCaRT (n=450) |
|--|---|
| Non inferiority boundary | 8% |
| centers | 24 |
| surgeons | Video-Assessment ≥ 30 lap. Rectum / ≥ 100 lap. colon |
| Tumour stages | I-III |
| Neoadjuvant chemoradiation | 49.5% |
| conversions | 9% |
| 2-yrs LRR, % (Δ; 95%CI) | 5.4 vs. 2.3 (2.3; -1.5 to 6.1) |
| 2-yrs DFS, % (Δ; 95%CI) | 80 vs. 82 (-2; -9.5 to 5.4) |

✓ no significant difference

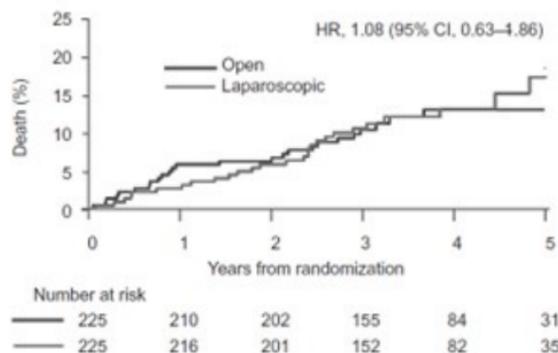
Stevenson ARL, Ann Surg 2019

Incidence of recurrence or death



A

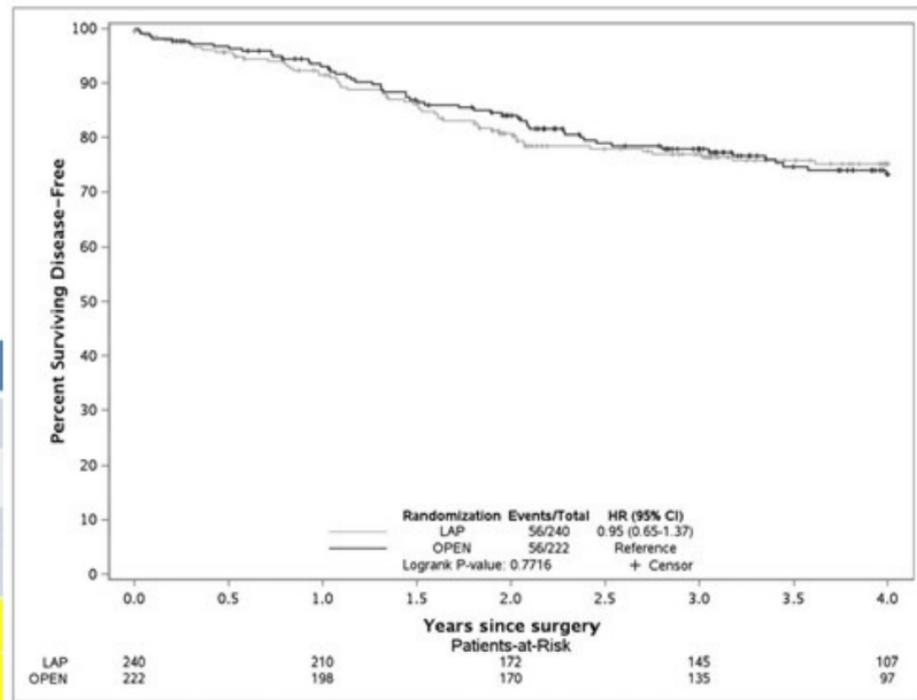
Incidence of death

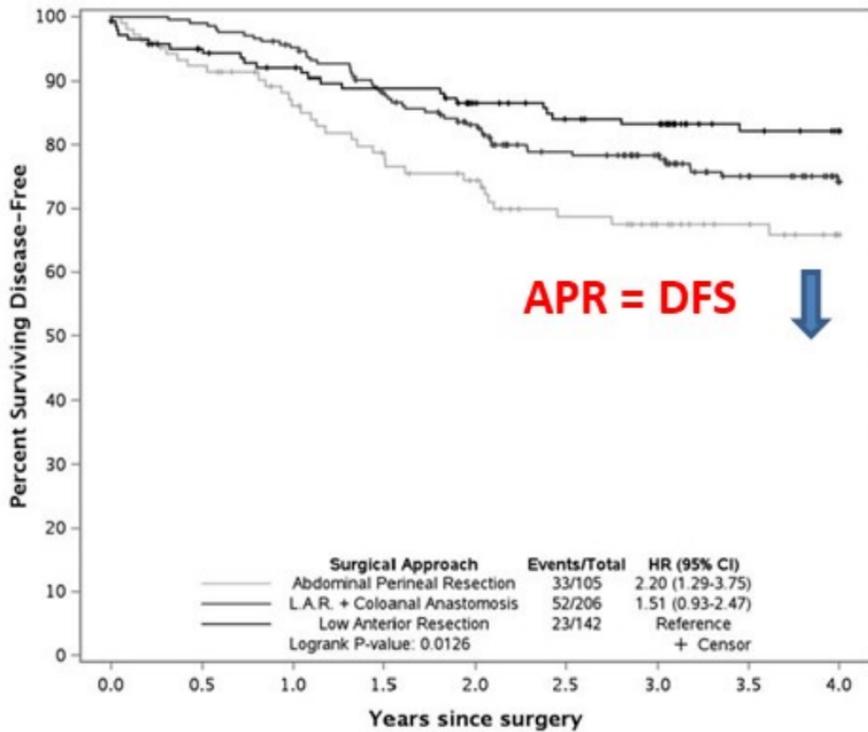


B

ACOSOG Z6051

| Lap. vs. open | ACOSOG (n=486) |
|-----------------------------|--|
| Non inferiority boundary | 6% |
| centers | 35 |
| surgeons | Video-Assessment ≥ 20 lap. Rectum |
| Tumour stages | II-III (T3 N0-2) |
| Neoadjuvant chemoradiation | Alle |
| conversions | 11.3% |
| 2-yrs DFS, % (95%CI) | 79.5 (74.4-84.9) vs. 83.2 (78.3-88.3) |





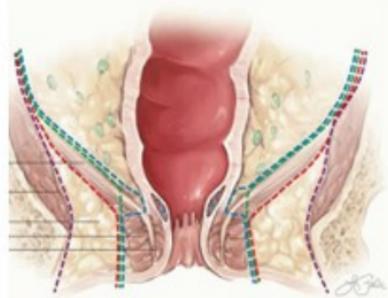
Abdominal Perineal Resection
L.A.R. + Coloanal Anastomosis
Low Anterior Resection

| | 0.0 | 0.5 | 1.0 | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 |
|-------------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Abdominal Perineal Resection | 105 | 83 | 67 | 50 | 37 | | | | |
| L.A.R. + Coloanal Anastomosis | 206 | 194 | 160 | 127 | 90 | | | | |
| Low Anterior Resection | 142 | 122 | 107 | 96 | | | | | |

Rectal perforations (specimen):

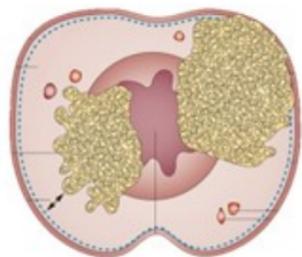
laparoscopic 15.4%
open 9.5%
p 0.054

APR 36%
LAR 4%
LAR + CAA 6%
p <0.0001



Laparoscopic vs open

- **Lower morbidity** for laparoscopy
- Data seems to demonstrate **oncologic equivalence**
- **CRM+** as most important predictor for local recurrence

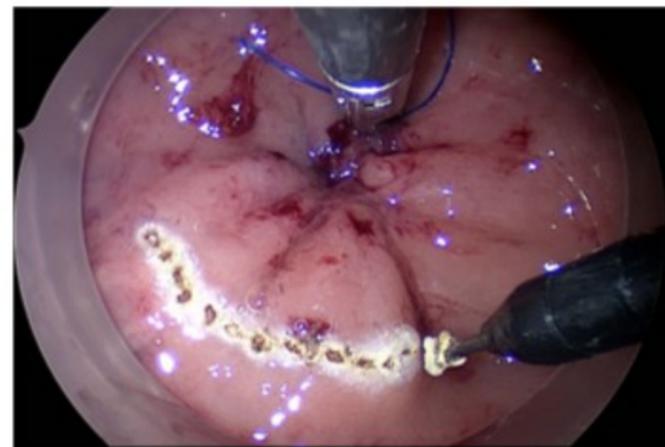
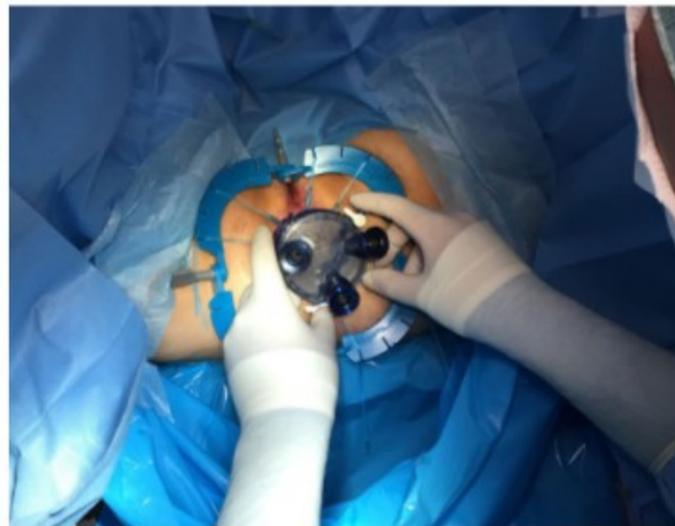
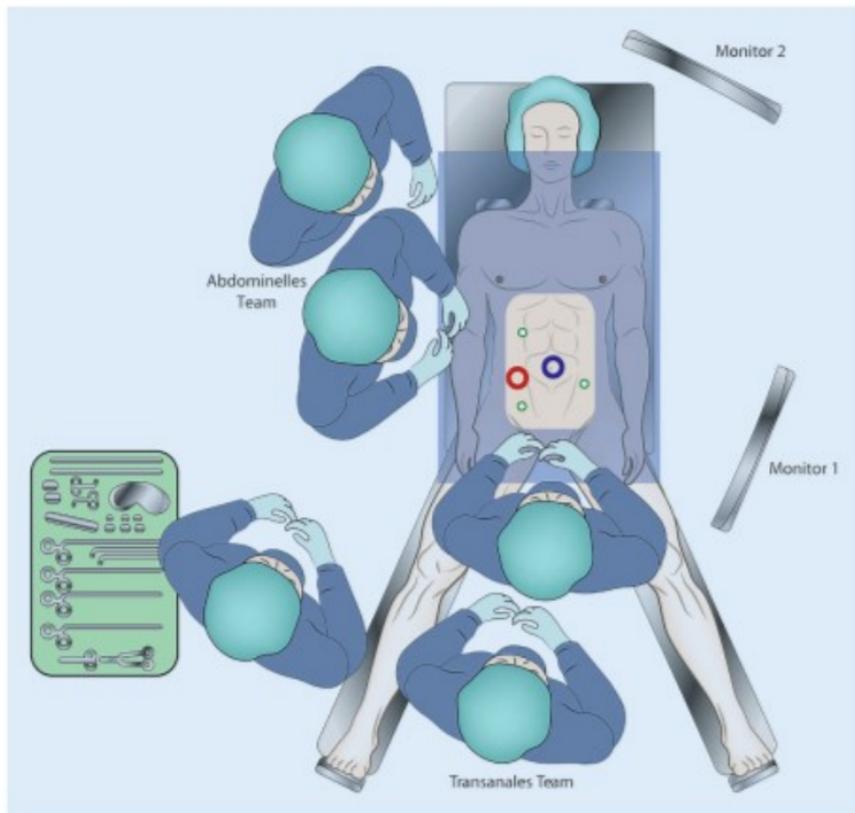


Laparoscopy

- **Caution in case of advanced tumours:** risk of inadvertent tumour perforation (APR) or compromised CRM
- Reduction of CRM+ in **TaTME or robotic TME?**



taTME



taTME

| Anticipated advantage | Risks |
|----------------------------------|---|
| Better exposure of distal rectum | Increased local recurrence? |
| Safe distal margin | Long flat learning curve |
| No coning | New complications: Urethral injury (0.8%), CO2-emboly |
| No double-stapling | |

Table 1. Characteristics of Patients Included in the Study

| Characteristic | Data |
|--|------------------------|
| Age, y, mean \pm SD | 65.5 \pm 12.7 |
| Sex, n (%) | |
| Male | 89 (63.6) |
| Female | 51 (36.4) |
| BMI, kg/m ² , mean \pm SD | 25.2 \pm 3.9 |
| American Society of Anesthesiologists score, n (%) | |
| I | 8 (5.7) |
| II | 117 (83.6) |
| III/IV | 15 (10.7) |
| Previous abdominal open surgery, n (%) | 35 (25.0) |
| Tumor location, n (%) | |
| Upper rectum | 29 (20.7) |
| Middle rectum | 70 (50.0) |
| Lower rectum | 41 (29.3) |
| Distance from anal verge by MRI, cm, mean \pm SD | 7.6 \pm 3.6 |
| Upper rectum | 12.6 \pm 1.9 |
| Middle rectum | 7.7 \pm 1.9 |
| Lower rectum | 3.6 \pm 1.2 |
| Preoperative T stage, n (%) | |
| mrT1 | 2 (1.4) |
| mrT2 | 27 (19.3) |
| mrT3 | 90 (64.3) |
| mrT4 | 11 (7.9) |
| Not assessed ^a | 10 (7.1) |
| Preoperative N stage, n (%) | |
| mrN- | 71 (50.7) |
| mrN+ | 59 (42.1) |
| Not assessed ^a | 10 (7.1) |
| Preoperative M stage, n (%) | |
| M0 | 131 (93.6) |
| M1 ^b | 9 (6.4) |
| Neoadjuvant therapy, n (%) | |
| Chemoradiation | 90 (64.3) ^c |
| Chemotherapy | 3 (2.1) |
| Radiotherapy | 1 (0.7) |

taTME

- Barcelona, n=140, 2011-2014
- Anastomotic leakage 8.6%
- Quality:
 - Complete 91.1%
 - Nearly complete 2.1%
 - Incomplete 0.7%
 - CRM <1mm 6.4%
- Follow-up **15 months**
 - **LRR 2.3%**
 - Disease free 90.8%

Lacy AM, Wexner SD, Heald RJ. Surg Endosc 2015

taTME vs lap. TME

| Characteristic | taTME | laTME | P value |
|--|-----------------------------|-----------------------------|---------|
| Gender, n (%) | | | 0.724 |
| Male | 83 (64.8%) | 89 (66.9%) | |
| Female | 45 (35.2%) | 44 (33.1%) | |
| Age in years, mean \pm SD (range) | 56.1 \pm 11.2 (26.0–78.0) | 56.1 \pm 10.9 (26.0–75.0) | 0.270 |
| BMI in kg/m ² , mean \pm SD (range) | 22.5 \pm 3.1 (17.0–33.2) | 22.2 \pm 2.9 (14.2–31.6) | 0.536 |
| Historical of abdominal surgery, n (%) | | | 0.160 |
| Yes | 10 (7.8%) | 5 (3.8%) | |
| No | 118 (92.2%) | 128 (96.2%) | |
| Distance between tumor and anus in cm, mean \pm SD (range) | 5.0 \pm 1.7 (1.5–10) | 5.1 \pm 1.5 (2.8–9.3) | 0.509 |
| Tumor large size in cm, mean \pm SD (range) | 3.2 \pm 1.3 (1.1–7.4) | 3.0 \pm 1.3 (0.6–8.0) | 0.150 |
| Neoadjuvant chemoradiation, n (%) | | | 0.100 |
| Yes | 59 (46.1%) | 48 (36.1%) | |
| No | 69 (53.9%) | 85 (63.9%) | |
| Both of radiotherapy and chemotherapy | 21 (16.4%) | 15 (11.3%) | |
| Only chemotherapy | 38 (29.7%) | 33 (24.8%) | |
| Preoperative T stage, n (%) | | | 0.560 |
| T0 | 2 (1.6%) | 3 (2.3%) | |
| T1 | 3 (2.3%) | 2 (1.5%) | |
| T2 | 19 (14.8%) | 25 (18.8%) | |
| T3 | 100 (78.1%) | 102 (76.7%) | |
| T4 | 1 (0.8%) | 1 (0.8%) | |
| TX | 3 (2.3%) | 0 (0%) | |
| Preoperative N stage, n (%) | | | 0.241 |
| N0 | 76 (59.4%) | 85 (63.9%) | |
| N1 | 43 (33.6%) | 37 (27.8%) | |
| N2 | 6 (4.7%) | 11 (8.3%) | |
| NX | 3 (2.3%) | 0 (0%) | |

| Data | taTME | laTME | P value |
|---|-------------------------|-------------------------|---------|
| Mesorectal resection quality, n (%) | | | 0.173 |
| Complete | 121 (94.5%) | 119 (89.5%) | |
| Nearly complete | 7 (5.5%) | 14 (10.5%) | |
| Incomplete | 0 (0%) | 0 (0%) | |
| Length of resected intestine in centimeter (cm), mean \pm SD (range) | 11.9 \pm 4.6 (6–36) | 11.7 \pm 4.2 (2.4–39) | 0.841 |
| Length between tumor and distal resection margin in cm, mean \pm SD (range) | 1.4 \pm 1.1 (0.1–8.0) | 1.3 \pm 0.9 (0–6.0) | 0.745 |
| Evaluated lymph nodes, median (range) | 15 (2–35) | 16 (0–66) | 0.069 |
| Distal resection margin status | | | 0.498 |
| Positive | 0 (0%) | 2 (1.5%) | |
| Negative | 128 (100%) | 131 (98.5%) | |
| CRM status | | | 0.674 |
| Positive | 2 (1.6%) | 2 (1.5%) | |
| Negative | 126 (98.4%) | 131 (98.5%) | |

NCT02966483, estimated enrollment 1114 patients
Preliminary results of RCT (128 vs 133 patients).
No difference in pathological outcome.

Bordeaux RCT

- 50 taTME vs 50 lap TME
- Distance from anal verge 4 (2-6) cm
- Follow-up 60 months

| | taTME | lapTME | p |
|---------------------------------------|----------|----------|-------|
| Positive distal margin | 2% | 8% | 0.362 |
| CRM + | 4% | 18% | 0.025 |
| Quality incomplete/nearly/complete, % | 12/18/70 | 12/26/62 | 0.616 |
| 5-yr LRR | 2.6% | 4.8% | 0.300 |
| 5-yr DFS | 73.9% | 71.9% | 0.351 |

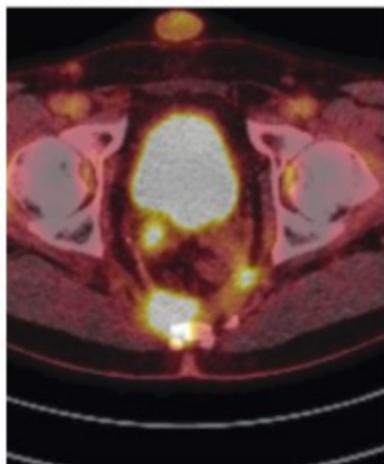
Norwegian Moratorium

- Norwegian Colorectal Cancer Registry: **3.4% LRR after TME**
- 110 taTME between 2015-2017 (20 Hospitals)
- **10 Local Recurrences (9%), median onset 11 months**
- **Rapid, multifocal growth in pelvic cavity and sidewalls (unusual pattern).**
- Neoadjuvant treatment in 30% (CRM at risk) in Norway, but 58% in taTME series
- No adjuvant Chemotherapy in stage I-III in Norway

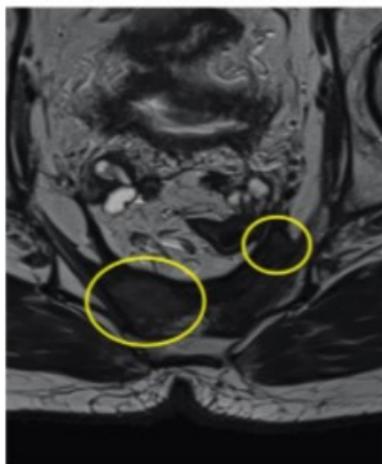
Netherlands

- **First 10 taTME** of 20 hospitals (n=120)
- CRM+ 5%, Anastomotic leakage 17%, **LRR 10% after 15 months**
- Prolonged cohort (266 patients): **LRR 4%**

a Multifocal recurrence



b Left lateral and presacral recurrence



c Recurrence in right seminal vesicle

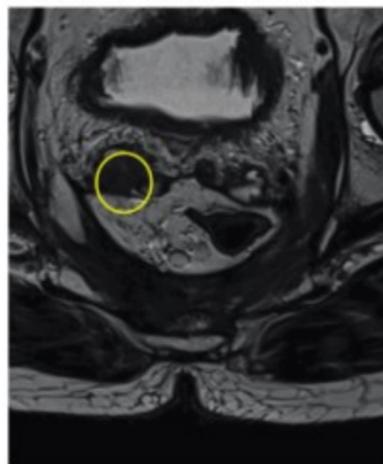


Table 6 Local recurrence according to number of transanal total mesorectal excision procedures at each centre in prolonged cohort

| | Local recurrence rate | | | Total |
|----------|-----------------------|---------------------|--------------------|-----------------|
| | Procedures 1-10 | Procedures 11-40 | Procedures ≥ 41 | |
| Centre A | 2 of 10 | 2 of 30 | 0 of 31 | 4 of 71 (6) |
| Centre B | 1 of 10 | 2 of 30 | 3 of 28 | 6 of 68 (9) |
| Centre C | 2 of 10 | 0 of 30 | 1 of 7 | 3 of 47 (6) |
| Centre D | 1 of 10 | 1 of 30 | 0 of 40 | 2 of 80 (3) |
| Overall | 6 of 40 (15) | 5 of 120 (4.2) | 4 of 106 (3.8) | 15 of 266 (5.6) |

Values in parentheses are percentages.

COLOR III

COLOR III: a multicentre randomised clinical trial comparing transanal TME versus laparoscopic TME for mid and low rectal cancer

Charlotte L. Deijen¹ · Simone Velthuis² · Alice Tsai³ · Stella Mavroveli³ ·
Elly S. M. de Lange-de Klerk¹ · Colin Sietses² · Jurriaan B. Tuijnman¹ ·
Antonio M. Lacy⁴ · George B. Hanna³ · H. Jaap Bonjer¹

Received: 3 April 2015 / Accepted: 15 September 2015 / Published online: 4 November 2015
© The Author(s) 2015. This article is published with open access at Springerlink.com

- 1100 Patients (669 taTME, 335 laparoscopic)
- Primary endpoint: **Involved CRM**
- **Superiority** trial (estimated CRM+ 7% in lap TME vs 3% in taTME)

Robotic TME



Advantages:

- 3D View
- Articulated instruments
- Advantage in narrow spaces

Robotic TME vs lap. TME

- RCT, 163 patients, 2 surgeons
- cT1-3NxM0, mid and low rectum
- stratified per sex and administration of preoperative chemoradiotherapy
- primary outcome was the **quality of total mesorectal excision** (TME) specimen

Robotic TME vs lap. TME

TABLE 1. Demographic and Clinical Characteristics of Randomly Assigned Patients (n = 139)

| | RG (n = 66) | LG (n = 73) | P |
|---|----------------|----------------|-------|
| Age, yrs, mean (SD) | 60.4 (9.7) | 59.7 (11.7) | 0.693 |
| Sex, n (%) | | | 0.417 |
| Male | 51 (77.3) | 52 (71.2) | |
| Female | 15 (22.7) | 21 (28.8) | |
| BMI, mean (SD) | 24.1 (3.3) | 23.6 (3.0) | 0.327 |
| ASA grade, n (%) | | | 0.185 |
| I | 20 (30.3) | 30 (41.1) | |
| II | 46 (69.7) | 43 (58.9) | |
| History of surgery, n (%) | | | 0.105 |
| Yes | 16 (24.2) | 27 (37.0) | |
| No | 50 (75.8) | 46 (63.0) | |
| Family history of cancer, n (%) | | | 0.630 |
| Colon cancer | 6 (9.1) | 8 (10.9) | |
| Other than colon cancer | 24 (36.4) | 31 (42.5) | |
| Unknown cancer | 1 (1.5) | 0 (0) | |
| None | 35 (53.0) | 34 (46.6) | |
| Tumor location from anal verge, cm, n (%) | | | 0.809 |
| ≤5 | 33 (50.0) | 35 (48.0) | |
| >5 | 33 (50.0) | 38 (52.0) | |
| Preoperative CEA level, ng/mL, n (%) | | | 0.259 |
| ≤5 | 44 (66.7) | 55 (75.3) | |
| >5 | 22 (33.3) | 18 (24.7) | |
| Preoperative CRT, n (%) | | | 0.755 |
| Yes | 51 (77.3) | 58 (79.5) | |
| No | 15 (22.7) | 15 (20.5) | |

ASA indicates American Society of Anesthesiologists; BMI, body mass index; CEA, carcinoembryonic antigen; CRT, chemoradiotherapy; LG, laparoscopic group; RG, robotic group; SD, standard deviation.

TABLE 2. Operative Data (n = 139)

| | RG (n = 66) | LG (n = 73) | P |
|--|----------------|----------------|---------|
| Procedures, n (%) | | | 0.592 |
| Low anterior resection (DS) | 40 (60.6) | 48 (65.8) | |
| Low anterior resection (HS) | 25 (37.9) | 22 (30.1) | |
| Abdominoperineal resection | 1 (1.5) | 2 (2.7) | |
| Hartmann operation | 0 (0) | 1 (1.4) | |
| Diverting ileostomy, n (%) | | | 0.621 |
| Yes | 65 (98.5) | 70 (95.9) | |
| No | 1 (1.5) | 3 (4.1) | |
| Splenic flexure mobilization, n (%) | | | 0.455 |
| Yes | 9 (13.6) | 7 (9.6) | |
| No | 57 (86.4) | 66 (90.4) | |
| Operation time, min, mean (SD) | 339.2 (80.1) | 227.8 (65.6) | <0.0001 |
| Estimated blood loss, mL, median (range) | 100 (0–1000) | 50 (0–300) | <0.0001 |
| Conversion to open surgery, n (%) | | | 0.475 |
| Yes | 1 (1.5) | 0 (0) | |
| No | 65 (98.5) | 73 (100.0) | |
| Intraoperative adverse event, n (%) | | | 0.647 |
| None | 61 (92.4) | 70 (95.9) | |
| Bleeding | 3 (4.6) | 1 (1.4) | |
| Perforation of the rectum | 2 (3.0) | 2 (2.7) | |

DS indicates double-stapling anastomosis; HS, hand-sewn anastomosis; LG, laparoscopic group; RG, robotic group; SD, standard deviation.



Robotic TME vs lap. TME

- No difference in
 - Quality of TME
 - CRM
 - morbidity

| | Robotic | Laparoscopic | |
|---|----------------|---------------------|-------|
| 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) | |

ROLARR

- N=471, Primary endpoint: **conversion to open surgery**
- Konversionen: **Rob 9.1% vs Lap 12.2%, p=0.16**
- No difference for:
 - Morbidity
 - CRM +
 - Bladder and sexual function
- Costs \$1132 higher in Rob
- Limitations:
 - Fewer than 5 recruited patients per center
 - Experience in robotic surgery < laparoscopy
 - Inclusion of high and low rectal cancer, with and w/o neoadj. therapy

ROLARR: Subgroup males

eTable 4. Treatment x Sex Interaction Effects

| Effect | Laparoscopic surgery (No. conversions/ No. patients (%)) | Robotic surgery (No. conversions/ No. patients (%)) | Risk difference and 95% CI (unadjusted) | Odds ratio and 95% CI (adjusted)* | p-value |
|--|--|---|---|-----------------------------------|---------|
| Treatment in males: robotic surgery (vs. laparoscopic) | 25/156 (16.0) | 14/161 (8.7) | 7.3 (0.1, 14.6) | 0.455 (0.209, 0.987) | 0.0429 |
| Treatment in females: robotic surgery (vs. laparoscopic) | 3/74 (4.1) | 5/75 (6.7) | -2.6 (-9.8, 4.6) | 2.022 (0.425, 9.621) | 0.3757 |

0.0939**

*adjusted for BMI class, preoperative radiotherapy, intended procedure and operating surgeon

**p-value for the treatment effect is referring to a test of heterogeneity of treatment effect between the subgroups.

Odds ratios derived from the Treatment term and Treatment-by-Sex interaction term.

QoL: Propensity score analysis

| | Robot (n = 130) | Laparoscopy (n = 130) | P-value |
|-----------------------------|--------------------|--------------------------|---------|
| Age (years)* | 60.5 (10.1) | 60.0 (9.3) | 0.703 |
| Sex, n (%) | | | |
| Male | 95 (73.1) | 95 (73.1) | 1.000 |
| Female | 35 (26.9) | 35 (26.9) | |
| BMI (kg/m ²)* | 23.7 (3.2) | 23.3 (2.9) | 0.287 |
| Preoperative | | | |
| CCRT, n (%) | 63 (48.5) | 61 (46.9) | 0.901 |
| Tumour location (cm)* | 5.9 (2.7) | 6.3 (2.6) | 0.196 |
| Type of operation, n (%) | | | |
| Low anterior resection | 90 (69.2) | 91 (70.0) | 0.991 |
| Coloanal anastomosis | 38 (29.2) | 37 (28.5) | |
| Abdominoperineal excision | 2 (1.5) | 2 (1.5) | |
| Protective ileostomy, n (%) | 43 (33.1) | 37 (28.5) | 0.502 |
| Postoperative | | | |
| hospital stay (days)* | 9.0 (6.6) | 10.7 (14.2) | 0.228 |
| Complications, n (%) | | | |
| Anastomotic leakage | 12 (9.2) | 9 (6.9) | 0.751 |

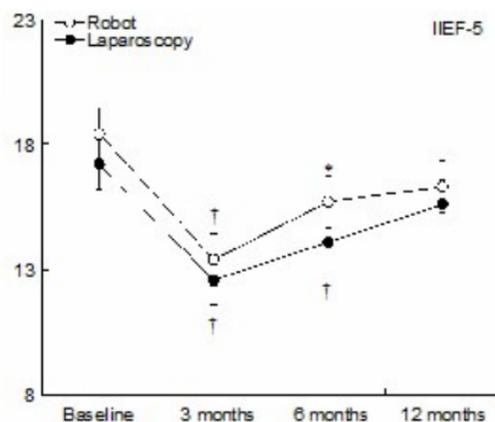
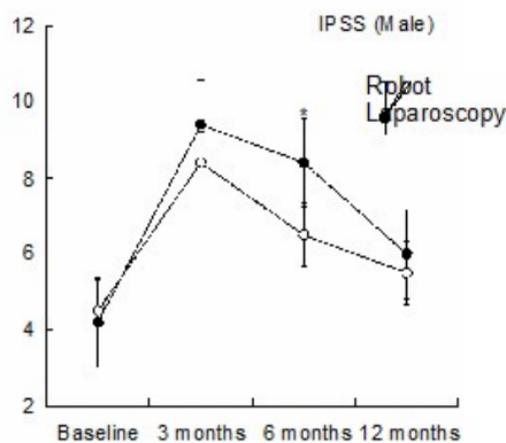


Figure 5 International Index of Erectile Function-5 (IIEF-5) scores. *P < 0.05 for difference in mean scores between groups. †P < 0.05 for difference in mean scores between baseline and each time point.



- International prostatic symptom score **less impaired in Robotic after 6 months**
- **Erectile function better in Robotic (6 months).**

Feng et al, Lancet September 7, 2022

1742 Patients / 11 hospitals/ 8 provinces

Age: 18 – 80 y

Middle (5-10cm) and low (<5cm) rectum

cT 1-3/ No-1/ no distant metastasis

3 - year locoregional recurrence rate

CRM +

30 day postop complications (Clavien-Dindo II and higher)

Feng et al, Lancet September 7, 2022

| | Rob-G | Lap-G | p = |
|---|-------------|-------------|--------|
| | n = 586 | n = 585 | |
| CRM+ (%) | 4 | 7.2 | 0.023 |
| Conversions to open procedure; n (%) | 1.7 | 3.9 | 0.021 |
| Intraop. Complications (%) | 5.5 | 8.2 | 0.030 |
| Complications CD II+ (%) | 16.2 | 23.1 | 0.003 |
| Anastomotic leakage (%) | 5.1 | 8.2 | 0.057 |
| Complete resection (%) | 95.4 | 91.8 | 0.042 |
| Hospital stay (days) | 7 | 8 | 0.0001 |
| Preventive stoma (%) | 26.5 | 26.1 | 0.866 |

Feng et al, Lancet September 7, 2022

Robotic surgery for middle and low rectal cancer by experienced surgeons could improve surgical quality compared with conventional laparoscopic surgery

Eigene Daten

| | Rob TME (n=68) | Lap TME (n=154) | p |
|---|--------------------|--------------------|-------|
| Age; median years (IQR) | 69 (57 – 81) | 66 (56 – 74) | 0.425 |
| Female gender | 17 (25) | 47 (31) | 0.297 |
| Body mass index: median (IQR) | 25 (22.32 – 27.37) | 25 (23,6 – 28) | 0.344 |
| Tumor distance from dental line: mean cm \pm SD | 8.7 \pm 2.43 | 8.63 \pm 1.81 | 0.982 |
| Neoadjuvant Chemoradiation | 100% | 100% | 1.0 |

| | Rob-G | Lap-G | p = |
|---|------------------------|------------------------|---------------|
| | n = 68 | n = 154 | |
| Operation time; median minutes (IQR) | 360 (300 – 427) | 305 (265 – 380) | 0.0001 |
| Conversions to open procedure (%) | 1.5 | 16.2 | 0.0082 |
| Stoma formation primary (%) | 50 | 89 | 0.0001 |
| | | | |
| Minor morbidity | 25 | 29 | 0.824 |
| Major morbidity (Clavien >3a) | 15 | 10 | 0.301 |
| Anastomotic leakage | 11.8 | 9.1 | 0.421 |
| Hospital stay; median days (IQR) | 13 (11-22) | 11.5 (10-16) | 0.221 |

Eigene Daten

| | Rob TME N = 68 | Lap TME N = 154 | P |
|-------------------------|-------------------|--------------------|---------|
| TME complete (%) | 88 | 89 | 0.828 |
| TME nearly complete (%) | 12 | 11 | 0.614 |
| TME incomplete (%) | 0 | 0 | |
| CRM; mean mm \pm SD | 19.6 \pm 10.5 | 19.5 \pm 11.5 | 0.958 |
| CRM+ (%) | 1.5 | 1.3 | > 0.999 |

Fazit

| | Open | Laparo- scopic | taTME | Robotic |
|------------------|---|-------------------|---|--|
| Oncological safe | ☑ | ☑ | <ul style="list-style-type: none"> • Large RCT pending • Learning curve | (☑) |
| Advantage | | | <ul style="list-style-type: none"> • Better exposure | <ul style="list-style-type: none"> • Better exposure • Less conversions in male (high BMI) |
| Risks | | | <ul style="list-style-type: none"> • Novel complications • LR in low volume | <ul style="list-style-type: none"> • Costs |
| Evidence | ☑ good | ☑ good | ✗ weak | ✗ weak |
| Subgroups | <ul style="list-style-type: none"> • T4 • Threatend CRM | „Standard“ | <ul style="list-style-type: none"> • Low tumours | <ul style="list-style-type: none"> • obese • male |