## **Supplemental Online Content**

Koskenvuo L, Lunkka P, Varpe P, et al. Morbidity after mechanical bowel preparation and oral antibiotics prior to rectal resection (MOBILE2): a randomized clinical trial. *JAMA Surg.* Published online March 20, 2024. doi:10.1001/jamasurg.2024.0184

eTable 1. List of Specific Complications Within 30 Days After Surgery

**eTable 2.** Prespecified Subgroup Analyses for Overall Postoperative Complications (CCI) and SSIs

eTable 3. Neoadjuvant Treatment According to Tumor Stage

This supplemental material has been provided by the authors to give readers additional information about their work.

| Clavien-Dindo grade and type - no. (%)               | Mechanical<br>bowel<br>preparation and<br>placebo<br>(N=288) | Mechanical and oral<br>antibiotic bowel<br>preparation<br>(N=277) |  |
|--|--|---|--|
| None   | 134 (46.5%)  | 155 (56.0%)   |  |
| 1 (one or more per patient)                          | 116 (40.3%)  | 109 (39.4%)   |  |
| Wound infection                                      | 5 (1.7)  | 2 (0.7%)  |  |
| Anastomotic dehiscence                               | 1 (0.3%)   | 0   |  |
| lleus (vomiting, nasogastric tube placement)         | 51 (17.7%)   | 48 (17.3%)  |  |
| Electrolyte imbalance                                | 16 (5.6%)  | 17 (6.1%)   |  |
| Collapse   | 4 (1.4%)   | 5 (1.8%)  |  |
| Urinary retention                                    | 13 (4.5%)  | 10 (3.6%)   |  |
| Incisional site bleeding (wound or anastomosis)      | 4 (1.4%)   | 5 (1.8%)  |  |
| Incision resuturation                                | 2 (0.7%)   | 1 (0.4%)  |  |
| Abnormal intensive incisional or operation site pain | 5 (1.7%)   | 1 (0.4%)  |  |
| Fever  | 5 (1.7%)   | 4 (1.4%)  |  |
| Problem with stoma site                              | 3 (1.0%)   | 8 (2.9%)  |  |
| Delirium   | 1 (0.3%)   | 1 (0.4%)  |  |
| Shortness of breath, Pain in chest                   | 6 (2.1%)   | 5 (1.8%)  |  |
| Peroneal nerve Paralysis                             | 0  | 1 (0.4%)  |  |
| 2 (one or more per patient)                          | 81 (28.1%)   | 47 (17.0%)  |  |
| Anastomotic dehiscence                               | 1 (0.3%)   | 0   |  |
| Abscess at anastomotic site                          | 2 (0.7%)   | 1 (0.4%)  |  |
| Wound infection                                      | 3 (1.0%)   | 4 (1.4%)  |  |
| Prolonged ileus with medication                      | 11 (3.8%)  | 6 (2.2%)  |  |
| Clostridium difficile infection                      | 0  | 1 (0.4%)  |  |
| Incisional site bleeding (wound or anastomosis)      | 13 (4.5%)  | 4 (1.4%)  |  |
| Urinary tract infection                              | 14 (4.9%)  | 6 (2.2%)  |  |
| Pneumonia  | 6 (2.1%)   | 5 (1.8%)  |  |
| Jrinary retention                                    | 4 (1.4%)   | 4 (1.4%)  |  |
| Pulmonary embolism                                   | 6 (2.1%)   | 3 (1.1%)  |  |
| TIA  | 2 (0.7%)   | 0   |  |
| Shortness of breath, Pain in chest                   | 3 (1.0%)   | 2 (0.7%)  |  |
| Other infection (bacteremia, cholecystitis)          | 4 (1.4%)   | 2 (0.7%)  |  |

## eTable 1. List of Specific Complications Within 30 Days After Surgery

| Atrial fibrillation                             | 2 (0.7%)  | 3 (1.1%)  |
|---|-----------|-----------|
| Delirium  | 2 (0.7%)  | 0         |
| Incisional site pain                            | 1 (0.3%)  | 0         |
| Collapse  | 0         | 1 (0.4%)  |
| Fever   | 7 (2.4%)  | 6 (2.2%)  |
| 3a (one or more per patient)                    | 16 (5.6%) | 8 (2.9%)  |
| Anastomotic dehiscence, endoscopic management   | 9 (3.1%)  | 2 (0.7%)  |
| Abscess at anastomotic site, drainage           |           |           |
|   | 3 (1.0%)  | 2 (0.7%)  |
| Prolonged ileus with intervention               | 1 (0.3%)  | 1 (0.4%)  |
| Incisional site bleeding (wound or anastomosis) | 1 (0.3%)  | 3 (1.1%)  |
| Ascites   | 1 (0.3%)  | 0         |
| Headache, epidural blood patch                  | 1 (0.3%)  | 0         |
| 3b (one or more per patient)                    | 23 (8.0%) | 10 (3.6%) |
| Anastomotic dehiscence                          | 9 (3.1%)  | 6 (2.2%)  |
| Abscess at anastomotic site                     | 2 (0.7%)  |           |
| Colonic perforation above anastomosis           | 1 (0.3%)  |           |
| Fascial dehiscence                              | 3 (1.0%)  | 2 (0.7%)  |
| Stoma revision                                  | 3 (1.0%)  | 1 (0.4%)  |
| Prolonged ileus with intervention               | 2 (0.7%)  | 0         |
| Incisional site bleeding (wound or anastomosis) | 1 (0.3%)  | 0         |
| Intestinal strangulation                        |           |           |
|   | 1 (0.3%)  |           |
| Intestinal perforation                          | 1 (0.3%)  | 0         |
| Incision resuturation                           | 0         | 1 (0.4%)  |
| 4a (one or more per patient)                    | 7 (3.1%)  | 5 (1.8%)  |
| Anastomotic dehiscence                          | 1 (0.3%)  | 1 (0.4%)  |
| Dyspnea   | 3 (1.0%)  | 1 (0.4%)  |
| Epileptic seizure                               | 1 (0.3%)  | 0         |
| Pneumonia                                       | 1 (0.3%)  | 0         |
| AKI   | 1 (0.3%)  | 0         |
| Hypotension                                     | 0         | 1 (0.4%)  |
| Cardiac failure                                 | 0         | 1 (0.4%)  |
| Intra-abdominal bleeding                        | 0         | 1 (0.4%)  |
| 4b (one or more per patient)                    | 4 (1.4%)  | 0         |

| Anastomotic dehiscence      | 4 (1.4%)                     | 0                            |
|-----------------------------|------------------------------|------------------------------|
| 5 (equals death)            | <b>1 (0.3%)</b> <sup>a</sup> | <b>2 (0.7%)</b> <sup>a</sup> |
| Acute myocardial infarction | 0                            | 1 (0.4%)                     |
| Anastomotic dehiscence      | 0                            | 1 (0.4%)                     |
| Aspiration pneumonia        | 1 (0.3%)                     | 0                            |

Data is presented as numbers (%s).

TIA, transient ischemic attack; AKI, acute kidney injury.

<sup>a</sup>A total of five patients died within 90 days, but this table shows complications and mortality up to 30 days.

**eTable 2.** Prespecified Subgroup Analyses for Overall Postoperative Complications (CCI) and SSIs

| Subgroup         |  | Mechanical<br>bowel<br>preparation<br>and placebo | Mechanical<br>and oral<br>antibiotic<br>bowel<br>preparation | Effect size (OR<br>[95% Cl] or r) | p value <sup>t</sup> |
|------------------|--|---|--|-----------------------------------|----------------------|
| Tumor            | location                                     |   |  |                                   |                      |
| Lower e<br>verge | edge < 10cm from the anal                    | N=192   | N=191  |                                   |                      |
|                  | CCIª, median (IQR)                           | 8.6603 (0-<br>22.21)                              | 0 (0-8.66)   | 0.8147                            | 0.0003               |
|                  | SSI, n (%)                                   | 40 (20.8)   | 15 (7.9)   | 0.324 (0.172-                     | 0.0003               |
|                  | Superficial                                  | 3 (1.6%)  | 5 (2.6%)   | 0.609)                            |                      |
|                  | Deep   | 3 (1.6%)  | 1 (0.5%)   |                                   |                      |
|                  | Organ  | 34 (17.7%)  | 9 (4.7%)   |                                   |                      |
| Lower e<br>verge | edge ≥ 10cm from the anal                    | N=96  | N=86   |                                   |                      |
|                  | CCI <sup>a</sup> , median (IQR)              | 0 (0-20.92)                                       | 0 (0-9.56)   | 0.0749                            | 0.312                |
|                  | SSI, n (%)                                   | 8 (8.3)   | 8 (9.3)  | 1.128 (0.404-                     | 0.818                |
|                  | Superficial                                  | 2 (2.1%)  | 1 (1.2%)   | 3.148)                            |                      |
|                  | Deep   | 1 (1.0%)  | 0  |                                   |                      |
|                  | Organ/space                                  | 5 (5.2%)  | 7 (8.1%)   |                                   |                      |
| Neoadj           | uvant treatment                              |   |  |                                   |                      |
|                  | hort-course radiotherapy with<br>ate surgery | N=233   | N=224  |                                   |                      |
|                  | CCIª, median (IQR)                           | 8.6603 (0-<br>20.92)                              | 0 (0-8.66)   | 0.1725                            | 0.0003               |
|                  | SSI, n (%)                                   | 40 (17.2)   | 12 (5.4)   | 0.273 (0.139-                     | <0.0001              |
|                  | Superficial                                  | 5 (2.1%)  | 3 (1.3%)   | 0.536)                            |                      |
|                  | Deep   | 3 (1.3%)  | 0  |                                   |                      |
|                  | Organ/space                                  | 32 (13.7%)  | 9 (4.0%)   |                                   |                      |
| Yes              |  | N=55  | N=53   |                                   |                      |
|                  | CCI <sup>a</sup> , median (IQR)              | 0 (0-20.92)                                       | 0 (0-14.79)  | 0.0299                            | 0.758                |
|                  | SSI, n (%)                                   | 8 (14.5)  | 11 (20.8)  | 1.539 (0.565-                     | 0.397                |
|                  | Superficial                                  | 0   | 3 (5.7%)   | 4.188)                            |                      |
|                  | Deep   | 1 (1.8%)  | 1 (1.9%)   |                                   |                      |

|         | Organ/space                     | 7 (12.7%)            | 7 (13.2%)   |               |        |
|---------|---------------------------------|----------------------|-------------|---------------|--------|
| Protect | tive ostomy                     |                      |             |               |        |
| Yes     |                                 | N=222                | N=196       |               |        |
|         | CCI <sup>a</sup> , median (IQR) | 8.6603 (0-<br>22.64) | 0 (0-8.66)  | 0.1865        | 0.0001 |
|         | SSI, n (%)                      | 40 (18.0)            | 16 (8.2)    | 0.404 (0.219- | 0.0032 |
|         | Superficial                     | 3 (1.4%)             | 5 (2.6%)    | 0.748)        |        |
|         | Deep                            | 4 (1.8%)             | 1 (0.5%)    |               |        |
|         | Organ/space                     | 33 (14.9%)           | 10 (5.1%)   |               |        |
| No      |                                 | N=66                 | N=81        |               |        |
|         | CCIª, median (IQR)              | 0 (0-20.92)          | 0 (0-12.25) | 0.0065        | 0.937  |
|         | SSI, n (%)                      | 8 (12.1)             | 7 (8.6)     | 0.686 (0.235- | 0.488  |
|         | Superficial                     | 2 (3.0%)             | 1 (1.2%)    | 2.001)        |        |
|         | Deep                            | 0                    | 0           |               |        |
|         | Organ/space                     | 6 (9.1%)             | 6 (7.3%)    |               |        |
| Surgica | al approach                     |                      |             |               |        |
| Open    |                                 | N=226                | N=214       |               |        |
|         | CCI <sup>a</sup> , median (IQR) | 8.6603 (0-<br>21.35) | 0 (0-9.56)  | 0.1498        | 0.002  |
|         | SSI, n (%)                      | 40 (17.7)            | 18 (8.4)    | 0.427 (0.236- | 0.0040 |
|         | Superficial                     | 4 (1.8%)             | 6 (2.8%)    | 0.771)        |        |
|         | Deep                            | 3 (1.3%)             | 1 (0.5%)    |               |        |
|         | Organ/space                     | 33 (14.6%)           | 11 (5.1%)   |               |        |
| Minima  | Ily invasive                    | N=62                 | N=63        |               |        |
|         | CCI <sup>a</sup> , median (IQR) | 0 (0-20.92)          | 0 (0-8.66)  | 0.1325        | 0.139  |
|         | SSI, n (%)                      | 8 (12.9)             | 5 (7.9)     | 0.582 (0.179- | 0.363  |
|         | Superficial                     | 1 (1.6%)             | 0           | 1.888)        |        |
|         | Deep                            | 1 (1.6%)             | 0           |               |        |
|         | Organ/space                     | 6 (9.7%)             | 5 (7.9%)    |               |        |

Data is presented as medians with IQRs or numbers (%s).

CCI, comprehensive complication index; SSI, surgical site infection; OR, odds ratio; CI, confidence interval; IQR, interquartile range.

<sup>a</sup>Not normally distributed; hence, effect size is given as Wilcoxon effect size

<sup>b</sup>After Bonferroni correction for multiple comparisons, a p-value < 0.003125 is considered statistically significant (bold).

|   | Stage 1 | Stage 2 | Stage 3 | Stage 4 | All     |
|---|---------|---------|---------|---------|---------|
|   | n (%)   |
| No  | 105     | 88      | 125     | 9       | 327     |
|   | (99.1%) | (84.6%) | (45.6%) | (36.0%) | (64.2%) |
| Short cource radiotherapy                     | 0       | 7       | 59      | 5       | 71      |
|   |         | (6.7%)  | (21.5%) | (20.0%) | (13.9%) |
| Short cource radiotherapy with delay          | 0       | 4       | 3       | 0       | 7       |
|   |         | (3.8%)  | (1.1%)  |         | (1.4%)  |
| Chemoradiotherapy                             | 1       | 5       | 84      | 6       | 96      |
|   | (0.9%)  | (4.8%)  | (30.7%) | (24.0%) | (18.9%) |
| Chemotherapy only                             | 0       | 0       | 0       | 5       | 5       |
|   |         |         |         | (20.0%) | (1.0%)  |
| Total neoadjuvant treatment with short cource | 0       | 0       | 3       | 0       | 3       |
| radiotherapy and chemotherapy                 |         |         | (1.1%)  |         | (0.6%)  |
| Total   | 106     | 104     | 274     | 25      | 509     |