Complications in Colorectal Surgery: Are they unavoidable? Are they your problem?

Ahmer A. Karimuddin
General & Colorectal Surgery
• Screed:
  – A long speech, described as tedious
  – A whining rant
• Complication:
  – Any deviation from the normal post-operative course
  – Unexpected turns that can occur in medicine
**Complication:**

*Clavien-Dindo Classification*

|  
| --- |
| **Definitions** |
| **I** | Any deviation from the normal postoperative course without the need for pharmacological treatment other than the “allowed therapeutic regimens”, or surgical, endoscopic and radiological interventions |
| **II** | Requiring *pharmacological* treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included. |
| **III** | Requiring *surgical, endoscopic or radiological intervention*. |
| **IV** | *Life-threatening complication* requiring critical care management; CNS complications including brain haemorrhage and ischemic stroke (excluding TIA), sub-arachnoidal bleeding. |
| **V** | *Death* of a patient |
Colorectal Cancer: Complications

- Postoperative Complications
  - Scope
  - Impact
    - System
    - Patient
    - Oncologic

"85% recover with no complications. 60% of the remaining 15% will have a slower recovery rate, and the remaining 40% of the 15% may need additional treatment."
Colorectal Cancer: Complications

• Postoperative Complications
  – Scope
  – Impact
    • System
    • Patient
    • Oncologic
Colorectal Cancer: Complications

• Postoperative Complications
  – Scope
  – Impact
    • System
    • Patient
    • Oncologic

IT'S NOT MY FAULT.
Colorectal Cancer: Complications

Postoperative Complications

• Scope
• Impact
  – System
  – Patient
  – Oncologic

• Strategies
  – Data Measurement and Quality Improvement
  – Enhanced Recovery
  – Prevention of Anastomotic Leak
  – SSI Prevention
  – DVT/VTE Strategies
  – Provincial Strategies
Colorectal Cancer: Scope

- Longo et al (DCR, 2000)

**Risk Factors for Morbidity and Mortality After Colectomy for Colon Cancer**


- 30% of patients had complications
- 20% Major Morbidity
  - (MI/PE/Reoperation/ventilation > 24 hours)
Colorectal Cancer: Scope

• Kirchhoff et al. (2010), Patient Saf Surg
  – Surgical Site Infection: 2-25% (Best estimate 10-15%)
  – Anastomotic Leak: 3-15%
  – Ileus: 8-12%

• Major risk factors:
  – Age
  – Male Gender
  – Malnutrition / Obesity
  – ASA Class
  – Cardiac Status
  – Anemia
Colorectal Cancer: Scope

• Garfinkle et al (DCR, 2017)

Is There a Role for Oral Antibiotic Preparation Alone Before Colorectal Surgery? ACS-NSQIP Analysis by Coarsened Exact Matching

Richard Garfinkle, M.D. • Jad Abou-Khalil, M.D., M.Sc. • Nancy Morin, M.D. • Gabriela Ghitulescu, M.D. • Carol-Ann Vasilevsky, M.D. • Philip Gordon, M.D. • Marie Demian, M.D.
Division of Colon and Rectal Surgery
Department of Surgery
University of British Columbia

27% of patients had complications
11% SSI rate
2.6% UTI
16% rate of major morbidity
Colorectal Cancer: Impact

• System Impact of Complications
    • 11% readmission rate at 30 days
  – Wick et al (DCR, 2011)
    • 29% readmission rate at 90 days
    • $9000 per readmission
      – Repeat investigations, treatment costs
Colorectal Cancer: Impact

Costs of complications after colorectal cancer surgery in the Netherlands: Building the business case for hospitals

J.A. Govaert a,b,*, M. Fiocco c,d, W.A. van Dijk e,f, A.C. Scheffer e, E.J.R. de Graaf g, R.A.E.M. Tollenaar a,i, M.W.J.M. Wouters a,h,i

On behalf of the Dutch Value Based Healthcare Study Group
Colorectal Cancer: Impact

Costs of complications after colorectal cancer surgery in the Netherlands: Building the business case for hospitals

J.A. Govaert a,b,*, M. Fiocco c,d, W.A. van Dijk e,f, A.C. Scheffer e, i, M.W.J.M. Wouters a,h,i, Ilealhealthcare Study Group¹

![Pie chart showing costs]

- Baseline cost of colorectal cancer care (all patients: n=6768)
- Additional costs of patients with mild complications (n=819)
- Additional costs of patients with severe complications (n=1426)
Colorectal Cancer: Impact

Costs of complications after colorectal cancer surgery in the Netherlands

J.A. Govaert a,b,⁎, E.I.P. de Graaf a,b

Bar graph showing the costs of complications after colorectal cancer surgery in the Netherlands. The graph compares the baseline cost of colorectal cancer surgery with additional costs for patients with no complications, mild complications, and severe complications. The costs are presented in Euros (€).
Any complication leads to a minimum increase of costs of care by Euro 4000
The Personal Financial Burden of Complications After Colorectal Cancer Surgery

Scott E. Regenbogen, MD, MPH\textsuperscript{1,2}; Christine M. Veenstra, MD\textsuperscript{3}; Sarah T. Hawley, PhD, MPH\textsuperscript{4}; Mousumi Banerjee, PhD\textsuperscript{1,5}; Kevin C. Ward, PhD, MPH\textsuperscript{6}; Ikuko Kato, PhD\textsuperscript{7,8}; and Arden M. Morris, MD, MPH\textsuperscript{1,2,4}

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No Complications, N = 713 (76)</th>
<th>Complications, N = 224 (24)</th>
<th>$P^a$</th>
</tr>
</thead>
</table>
The Personal Financial Burden of Complications After Surgery

Figure 2. Financial burden scores are illustrated according to reported postoperative complications. Patients who reported complications had significantly higher composite financial burden scores ($P < .001$ for trend) and were less likely to report none of the elements of financial burden.
Colorectal Cancer: Impact

The Personal Financial Burden of Complications After Colorectal Cancer Surgery

Scott E. Regenbogen, MD, MPH; Christine M. Veenstra, MD; Sarah T. Hawley, PhD, MPH; Mousumi Banerjee, PhD; Kevin C. Ward, PhD, MPH; Ikuko Kato, PhD; and Arden M. Morris, MD, MPH

TABLE 2. Association of Reported Complications With Financial Burden and Worry

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>No Complications, N = 713 (76%)</th>
<th>Complications, N = 224 (26%)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>“I had to use savings”</td>
<td>223 (31)</td>
<td>90 (40)</td>
<td>.01</td>
</tr>
<tr>
<td>“I had to borrow money or take out a loan”</td>
<td>81 (11)</td>
<td>41 (18)</td>
<td>.007</td>
</tr>
<tr>
<td>“I could not make payments on credit cards or other bills”</td>
<td>79 (11)</td>
<td>41 (18)</td>
<td>.005</td>
</tr>
<tr>
<td>“I cut down on spending for food and/or clothes”</td>
<td>191 (27)</td>
<td>86 (38)</td>
<td>.001</td>
</tr>
<tr>
<td>“I cut down on spending for health care for other family members”</td>
<td>34 (5)</td>
<td>15 (7)</td>
<td>.26</td>
</tr>
<tr>
<td>“I cut down on recreational activities”</td>
<td>237 (33)</td>
<td>92 (41)</td>
<td>.03</td>
</tr>
<tr>
<td>“I cut down on expenses in general”</td>
<td>336 (47)</td>
<td>115 (51)</td>
<td>.27</td>
</tr>
</tbody>
</table>

Patients with complications experience significantly more personal financial burden.
The Impact of Postoperative Complications on Long-term Quality of Life After Curative Colorectal Cancer Surgery

Sarah R. Brown, PhD,* Ronnie Mathew, MD,‡ Ada Keding, MSc,* Helen C. Marshall, MSc,* Julia M. Brown, MSc., and David G. Jayne, MD†

- Study based on MRC CLASICC trial
Colorectal Cancer: Impact

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Colorectal Cancer: Impact

The Impact of Postoperative Complications on Long-term Quality of Life After Curative Colorectal Cancer Surgery

Sarah R. Brown, PhD,

Julia M. Brown, MSc.
Patients with complications have worse Quality of Life outcomes even extending out to 3 years.
Colorectal Cancer: Impact

• Hornbrook et al, Kaiser-Permanente, 2011
  – QoL indicators in 640 patients having undergone surgery for Colorectal Cancer
  – Even at 7 years out from surgery, early complications had one of the most significant impacts on QoL
    • More than the presence of an ostomy
The worse the complication, the worse the long term cancer survival

Fig. 1 Overall survival as a function of the comprehensive complication index (CCI)
Major postoperative complications following elective resection for colorectal cancer decrease long-term survival but not the time to recurrence.

Recurrences occur at a similar interval, but have a worse prognosis.
Infectious Postoperative Complications Decrease Long-term Survival in Patients Undergoing Curative Surgery for Colorectal Cancer

A Study of 12,075 Patients

Avo Artinyan, MD, MS,*† Sonia T. Orcutt, MD,† Daniel A. Anaya, MD,*†‡ Peter Richardson, PhD,‡§
G. John Chen, MD, PhD, MPH,‡§ and David H. Berger, MD, MHC*M,†‡
Infectious Postoperative Complications Decrease Long-term Survival in Patients Undergoing Curative Surgery for Colorectal Cancer

A Study of

Avo Artinyan, MD, MS,*† Sonia T. Orcutt, MD; G. John Chen, MD, PhD, MPH,*‡
Infectious Postoperative Complications Decrease Long-term Survival in Patients Undergoing Curative Surgery for Colorectal Cancer

*Avo Artinyan, MI, G.*

Overall Survival

- No Complication (MS 41.9 months)
- Non-Infectious Complication (MS 39.3 months)
- Infectious Complication (MS 32.9 months)

Overall p < 0.001
Even minor infectious complications indicate worse long term outcomes. Causative? Associative?
Colorectal Cancer: Impact

Anastomotic Leak Is Not Associated With Oncologic Outcome in Patients Undergoing Low Anterior Resection for Rectal Cancer

James D. Smith, MD, Philip B. Paty, MD, José G. Guillem, MD, Larissa K. Temple, MD, Martin R. Weiser, MD, and Garrett M. Nash, MD

<table>
<thead>
<tr>
<th></th>
<th>Tumor Recurrence, HR (95% CI)</th>
<th>Local Recurrence, HR (95% CI)</th>
<th>Disease-Specific Survival, HR (95% CI)</th>
<th>Overall Survival, HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastomotic leak</td>
<td>2.32 (0.74–7.28)</td>
<td>1.19 (0.29–4.93)</td>
<td>1.71 (0.42–6.91)</td>
<td>0.89 (0.46–1.75)</td>
</tr>
<tr>
<td>Distance from anal verge (cm)</td>
<td>1.01 (0.95–1.07)</td>
<td>0.98 (0.88–1.10)</td>
<td>0.99 (0.92–1.06)</td>
<td>1.02 (0.97–1.07)</td>
</tr>
</tbody>
</table>
Oncological outcome following anastomotic leak in rectal surgery

E. Espín¹, M. A. Ciga³, M. Pera² and H. Ortiz⁴ on behalf of the Spanish Rectal Cancer Project

This study showed that the development of AL after sphincter-saving surgery for rectal cancer did not affect the risk of local recurrence, overall recurrence, overall survival or cancer-specific survival. However, the presence of an AL was significantly associated with a higher postoperative mortality rate and need for reoperation. Although
Colorectal Cancer: Complications

- Hendren et al (2010, DCR)
  - SEER Database review
  - 17,108 patients with stage 3 CRC
    - Median age 75
    - 18% of patients had a complication
    - Only 54% of patients with complications had chemotherapy vs 70% (p<0.0001) OR 1.76 (1.59-1.95)
    - Complications: OR 2.04 for initiation of ChT > 8 weeks after surgery
Colorectal Cancer: Complications

• Des Guetz et al. (EJ Cancer, 2010)
  – Meta analysis
  – 13,158 patients
  – > 8 week delay of CT
    • Decreases OS (RR 1.2 (1.15-1.26))
Cheung et al. (DCR, 2009)
- SEER database
- Stage 2/3 Rectal Cancer
- Median Interval of Surgery to ChT: 42 days
- 12% of patients waited > 3 or more months
- Median OS worse in those who waited > 12 weeks (54 vs 76 months, p <0.01)
- Post-operative Hospital stay single most important predictor of delay
  - (Age, Black)
Colorectal Cancer: Complications

• Bayraktar et al, U of Miami, 2010
  – Chemotherapy started after 60 days post-op in 26% of patients
  – 70% due to post-operative issues, 30% due to administrative issues
  – OR 2.07 of decreased Overall Survival

• Lima et al, U of Alberta, 2011
  – 1053 patients
  – Stage 3 colon cancer
  – 40% started treatment after 4 months from surgery
  – Those who started chemotherapy after 3 months, had a 2.1 OR towards decreased Overall Survival
Surgical complications and their implications for surgeons’ well-being

A. Pinto, O. Faiz, C. Bicknell and C. Vincent
Division of Surgery, Department of Surgery and Cancer, St Mary’s Campus, Imperial College London, Norfolk Place, London W2 1PG, UK
Correspondence to: Dr A. Pinto (e-mail: a.pinto@imperial.ac.uk)

Collateral damage: The effect of patient complications on the surgeon’s psyche

Amit M. Patel, MD, Nichole K. Ingalls, MD, M. Ashraf Mansour, MD, Stanley Sherman, MD, Alan T. Davis, PhD, and Mathew H. Chung, MD, Grand Rapids, MI
Colorectal Cancer: Complications

Surgical complications and their implications for surgeons’ well-being

60% felt it was difficult to handle emotional impact of complications

Complications can impact functioning for up to 3 weeks

70% of surgeons attribute complications to their own errors
Colorectal Cancer: Complications

• Complications Happen
  – 20-30% of patients

• Complications Matter
  – Costs
    • Financial, Oncological and Patient Recovery

• Complications can be Prevented
Colorectal Cancer: Measurement

- Born from the VA Surgical Quality Improvement Program
- Non VA Hospitals brought on in 2005
- Now a Global Program
  - United States
  - Canada
  - Mexico
  - Saudi Arabia
• Data collected directly from patient charts

• Trained Surgical Clinical Reviewers/Abstracters
  – Specifically trained
  – Routinely audited
  – > 99% collection agreement rate
• ~ 135 variables
  – Demographics
  – Comorbidities
    • Risk stratification
  – Operative Information
  – 30 day outcomes
• Usually 1 in 5 case sampling
• NSQIP reports data back to hospitals.

• Hospitals act on their data.

• Hospitals monitor their interventions with ongoing data.
NSQIP

• Identify areas for quality improvement.

• Improve patient care and outcomes.

• Decrease institutional healthcare costs
NSQIP: Does it work?

• Change in data management routines
• Hiring of new staff
  – Specific training
• > 150k per site enrolled

• Does it work?
NSQIP: Does it work?

• Does it work?
  – Improve clinical outcomes
  – Change practice if needed
  – Cost effective
NSQIP: Does it work?

Improved Surgical Outcomes for ACS NSQIP Hospitals Over Time

**Evaluation of Hospital Cohorts With up to 8 Years of Participation**

Mark E. Cohen, PhD,* Yaoming Liu, PhD,† Clifford Y. Ko, MD, MS, MSHS, FACS,‡‡
and Bruce L. Hall, MD, PhD, MBA, FACS*§¶

![Graph showing improved outcomes over time](image-url)
NSQIP: Does it work?

Original Investigation

Association of Hospital Participation in a Surgical Outcomes Monitoring Program With Inpatient Complications and Mortality

David A. Etzioni, MD, MSHS; Nabil Wasif, MD, MPH; Amylou C. Dueck, PhD; Robert R. Cima, MD; Samuel F. Hohmann, PhD; James M. Naessens, ScD; Amit K. Mathur, MD, MS; Elizabeth B. Habermann, PhD, MPH

Figure 2. Adjusted Rates of Complications, Serious Complications, and Mortality by Hospital NSQIP Participation and Year

NSQIP, National Surgical Quality Improvement Program. Error bars indicate 95% CIs. Adjusted for patient comorbidity, operation type, age, and sex.
Secular, time-based trends seen, but NO relationship with NSQIP Participation!
RESEARCH ARTICLE

Change in Adverse Events After Enrollment in the National Surgical Quality Improvement Program: A Systematic Review and Meta-Analysis

Joshua Montroy¹, Rodney H. Breau¹,³,⁴*, Sonya Cnossen¹, Kelsey Witiuk¹, Andrew Binette², Taylor Ferrier², Luke T. Lavallée⁴, Dean A. Fergusson¹,³, David Schramm¹,³,⁵
NSQIP: Does it work?

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Focused on Intervention vs Passive Observation
NSQIP: Does it work?

Data is important, but it's what you do with it.
Quality improvement in gastrointestinal surgical oncology with American College of Surgeons National Surgical Quality Improvement Program

Donald J. Lucas, MD, MPH,¹ and Timothy M. Pawlik, MD, MPH, PhD,² Bethesda and Baltimore, MD
Quality improvement in gastrointestinal surgical oncology with American College of Surgeons National Surgical Quality Improvement Program

Donald J. Lucas, MD, MPH, and Timothy M. Pawl

<table>
<thead>
<tr>
<th>Complication</th>
<th>Odds Ratio</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Complication</td>
<td>+</td>
<td>0.95 (0.94, 0.96)</td>
</tr>
<tr>
<td>Death</td>
<td></td>
<td>1.03 (0.99, 1.07)</td>
</tr>
<tr>
<td>Superficial SSI</td>
<td>+</td>
<td>0.94 (0.92, 0.96)</td>
</tr>
<tr>
<td>Deep SSI</td>
<td></td>
<td>0.97 (0.93, 1.01)</td>
</tr>
<tr>
<td>Organ Space SSI</td>
<td></td>
<td>1.00 (0.97, 1.02)</td>
</tr>
<tr>
<td>Dehiscence</td>
<td></td>
<td>0.93 (0.89, 0.97)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>+</td>
<td>0.92 (0.89, 0.95)</td>
</tr>
<tr>
<td>UTI</td>
<td>+</td>
<td>0.96 (0.93, 0.99)</td>
</tr>
<tr>
<td>Reintubation</td>
<td></td>
<td>0.95 (0.93, 0.98)</td>
</tr>
<tr>
<td>Ventilator &gt; 48 h</td>
<td>+</td>
<td>0.93 (0.90, 0.95)</td>
</tr>
<tr>
<td>PE</td>
<td></td>
<td>0.92 (0.87, 0.98)</td>
</tr>
<tr>
<td>DVT</td>
<td></td>
<td>0.97 (0.93, 1.02)</td>
</tr>
<tr>
<td>Sepsis</td>
<td>+</td>
<td>0.92 (0.90, 0.94)</td>
</tr>
<tr>
<td>Septic Shock</td>
<td></td>
<td>0.85 (0.82, 0.88)</td>
</tr>
<tr>
<td>Reoperation</td>
<td>+</td>
<td>0.93 (0.91, 0.96)</td>
</tr>
</tbody>
</table>
NSQIP: Does it work?

• Cost effective?
  – Short answer: We don’t know.
  – Cost per adverse event is $12000 in Canada
    • 10-15 fewer adverse events pays for investment
  – If adverse events decrease, cost avoidance could be seen
    • 2 million USD per 10,000 General Surgery cases
  – Unanswered question
NSQIP: How was it used at St Paul’s?

• St Paul’s Hospital
  – Urban, downtown hospital
  – Mission to serve the downtown East side population
  – Quartenary Care/Provincial Referral site for:
    • HIV, Renal Diseases
    • Heart and Lung
    • Hematological Problems
    • Colorectal Surgery
NSQIP: St Paul’s and UTIs

Urinary Tract Infection
SPH vs All NSQIP
Unadjusted Data

% Cases Reviewed with UTI


SPH
SPH Baseline Median
NSQIP Median
Extended Baseline Median
Post Intervention Median
NSQIP All Practices
NSQIP: St Paul’s and UTIs

• What are we doing for Catheters?
  – Colon Cases (non-pelvic dissection)
    • Catheters are not placed, or removed in the OR
    • If left in, standing order for catheters to be removed on POD 1
NSQIP: St Paul’s and UTIs

• What are we doing for Catheters?
  – Rectal cases (Pelvic dissection)
    • Standing order for catheters to be removed on POD 2
NSQIP: St Paul’s and UTIs

• Since 2016
  – Tamsulosin (Flomax) starting on pre Op Day 3 till discharge
  – Men, > 50

• In early days, no impact on change in UR rates, but still trying!
NSQIP: St Paul’s and SSIs

Multiple impact points
- Surgical offices
- Pre Admission Clinic
- Pre-op Int Medicine consultations
- Check in at Day Care
- Anesthetic Induction
- Intra-operative
- Recovery Room
- Ward

Reduce SSI rates**
Surgical Site Infection Rates Following Implementation of a Colorectal Closure Bundle in Elective Colorectal Surgeries

Amandeep Ghuman, M.D.\textsuperscript{1} • Tiffany Chan, M.D.\textsuperscript{1}
Ahmer A. Karimuddin, M.D., F.R.C.S.C.\textsuperscript{2}
Carl J. Brown, M.D., F.R.C.S.C.\textsuperscript{2} • Manoj J. Raval, M.D., F.R.C.S.C.\textsuperscript{2}
P. Terry Phang, M.D., F.R.C.S.C.\textsuperscript{2}
Surgical Site Infection Rates Following Implementation of a Colorectal Closure Bundle in Elective Colorectal Surgeries

**TABLE 2. Surgical site infection rates**

<table>
<thead>
<tr>
<th></th>
<th>Preintervention (n = 111)</th>
<th>Postintervention (n = 94)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall SSI, %</td>
<td>25.2 (28)</td>
<td>26.6 (25)</td>
<td>0.82</td>
</tr>
<tr>
<td>Superficial, %</td>
<td>14.4 (16)</td>
<td>14.9 (14)</td>
<td>0.92</td>
</tr>
<tr>
<td>Deep and organ space, %</td>
<td>10.8 (12)</td>
<td>11.7 (11)</td>
<td>0.84</td>
</tr>
</tbody>
</table>

SSI = surgical site infection.
NSQIP: St Paul’s and SSIs

Antibiotics

Procedure Targeted

The ACS NSQIP Procedure Targeted optimally collects data on more than 30 high-risk, high-volume operations, including

- Colectomy
- Prostatectomy
- Lung lobectomy
- Multiple cranial nerve decompression

The ACS NSQIP procedure target identifies 15 high-risk procedures:

1. Cardiac surgery
   - Cardiac valve surgery
   - Coronary artery bypass surgery
2. Vascular surgery
   - Aortic reconstruction
   - Carotid endarterectomy
3. General surgery
   - Colectomy
   - Prostatectomy
   - Lung lobectomy
4. Neurosurgery
   - Multiple cranial nerve decompression
5. Other procedures
   - Electrophysiology procedures
   - Renal transplant

This procedure target is an essential component of the ACS NSQIP program, providing crucial data to improve patient outcomes and guide clinical decision-making.
NSQIP: St Paul’s and SSIs

- Top film with high moisture vapour transmission rate to transpire exudate
- Absorbent layer
- Silicone adhesive wound contact layer
- Innovative airlock layer

Alexis®
Wound Protectors/Retractors

360° Wound Protection
360° Atraumatic Retraction
- Maximizes exposure, minimizes incision size
- Offers ultimate versatility
NSQIP: St Paul’s and SSIs

Meta-analysis of negative-pressure wound therapy for closed surgical incisions

N. Hyldig\textsuperscript{1,2}, H. Birke-Sorensen\textsuperscript{4}, M. Kruse\textsuperscript{3}, C. Vinter\textsuperscript{2}, J. S. Joergensen\textsuperscript{2}, J. A. Sorensen\textsuperscript{1}, O. Mogensen\textsuperscript{2}, R. F. Lamont\textsuperscript{2,5} and C. Bille\textsuperscript{1}

Number Needed to Treat:

10

Cost

$180
NSQIP: St Paul’s and SSIs

RESEARCH ARTICLE

Wound Edge Protectors in Open Abdominal Surgery to Reduce Surgical Site Infections: A Systematic Review and Meta-Analysis

André L. Mihaljevic¹, Tara C. Müller¹, Victoria Kehl², Helmut Friess¹, Jörg Kleeff¹*

¹ Department of Surgery, Klinikum rechts der Isar, Technische Universität München, Ismaninger Strasse 22, 81675 Munich, Germany. ² Institute for Medical Statistics and Epidemiology, Klinikum rechts der Isar, Technische Universität München, Ismaninger Strasse 22, 81675 Munich, Germany

Number Needed to Treat: 8

Cost $170
NSQIP: St Paul’s and SSIs

- All patients receive Mechanical Bowel Prep and Oral Antibiotics pre-op
- All patients are given Chlorhexididine based scrubs to be used pre-operatively
- Chlorhexididine prep is used in the OR
- Alexis Wound Retractor is used for all cases (Open and MIS)
- All wounds > 5 cm have PICO dressing applied
NSQIP: St Paul’s and VTE

All Cases 07/01/11 - 06/30/12

Report/Site: 5625 / 0444

Hospital Odds Ratios

0.92 1.64 0.81 0.72 0.72 0.52 0.88 0.89 2.60 2.02 1.36

Outlier and Decile Status

ALLCASES Mortality  ALLCASES Morbidity  ALLCASES Cardiac  ALLCASES Pneumonia  ALLCASES Unplanned Intubation  ALLCASES Ventilator >48hrs.  ALLCASES DVT/PE  ALLCASES Renal Failure  ALLCASES UTI  ALLCASES SSI  ALLCASES ROR
Post-Hospital Discharge Venous Thromboembolism in Colorectal Surgery

Zhobin Moghadamyeghaneh¹ · Reza Fazl Alizadeh¹ · Mark H. Hanna¹ · Grace Hwang¹ · Joseph C. Carmichael¹ · Steven Mills¹ · Alessio Pigazzi¹ · Michael J. Stamos¹,²

Fig. 1 Timing of postoperative deep vein thrombosis and pulmonary embolism after operation in colorectal surgery

Fig. 3 Timing of venous thromboembolism in patients who were discharged from hospital within 4 days after colorectal operations
Most DVT and PE occur AFTER discharge.
Extended prophylaxis can prevent VTE after major abdominal surgery.
Prevention of VTE in Nonorthopedic Surgical Patients
Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines

3.6.6. For high-VTE-risk patients undergoing abdominal or pelvic surgery for cancer who are not otherwise at high risk for major bleeding complications, we recommend extended-duration pharmacologic prophylaxis (4 weeks) with LMWH over limited-duration prophylaxis (Grade 1B).
A Randomized Study on 1-Week Versus 4-Week Prophylaxis for Venous Thromboembolism After Laparoscopic Surgery for Colorectal Cancer.

- 225 randomized patients
- 113 short prophylaxis
- 112 extended prophylaxis
Even after MIS resections, extended prophylaxis reduces DVTs/PE
• All patients after colorectal cancer surgery, leave the hospital with 28 days of extended LMWH Prophylaxis
• Requires filling out of an exemption form to ensure coverage
  – Pharmacist on the ward helps with that
Postoperative Ileus—More than Just Prolonged Length of Stay?

Sarah E. Tevis¹ · Evie H. Carchman¹ · Eugene F. Foley¹ · Bruce A. Harms¹ · Charles P. Heise¹ · Gregory D. Kennedy¹

Risk factors for prolonged ileus following colon surgery

Zhobin Moghadamyeghaneh¹ · Grace S. Hwang¹ · Mark H. Hanna¹ · Michael Phelan² · Joseph C. Carmichael¹ · Steven Mills¹ · Alessio Pigazzi¹ · Michael J. Stamos¹,³

NSQIP 2012-2013
14% rate of POI
MIS Surgery protective
Rights >> Lefts
Clinical Practice Guidelines for Enhanced Recovery After Colon and Rectal Surgery From the American Society of Colon and Rectal Surgeons and Society of American Gastrointestinal and Endoscopic Surgeons

Joseph C. Carmichael, M.D.¹ • Deborah S. Keller, M.S., M.D.² • Gabriele Baldini, M.D.³
Liliana Bordeianou, M.D.⁴ • Eric Weiss, M.D.⁵ • Lawrence Lee, M.D., Ph.D.⁶
Marylise Boutros, M.D.⁶ • James McClane, M.D.⁷ • Liane S. Feldman, M.D.⁶
Scott R. Steele, M.D.⁸
NSQIP: Postoperative Ileus

Clinical Practice Guidelines for Enhanced Recovery After Colon and Rectal Surgery From the American Society of Colon and Rectal Surgeons and Society of American Gastrointestinal and Endoscopic Surgeons

- Minimally Invasive Surgery (1A)
- Regular Food Postoperatively ASAP (1B)
- Sham feeding/Chewing Gum (1B)
- Prevent excessive IV fluids (1B)
- Alvimopan (1B)
NSQIP: Postoperative Ileus

Early versus Traditional Postoperative Oral Feeding in Patients Undergoing Elective Colorectal Surgery: A Meta-Analysis of Randomized Clinical Trials

Cheng-Le Zhuang\textsuperscript{a} Xing-Zhao Ye\textsuperscript{a} Chang-Jing Zhang\textsuperscript{a} Qian-Tong Dong\textsuperscript{a} Bi-Cheng Chen\textsuperscript{b} Zhen Yu\textsuperscript{a}

**Decreases Ileus**
**NO increase in vomiting, aspiration or NG tube use! (None, NADA)**
NSQIP: Postoperative Ileus

A Meta-analysis on the Effect of Sham Feeding Following Colectomy: Should Gum Chewing Be Included in Enhanced Recovery After Surgery Protocols?

Yiu M. Ho, M.B.B.S.¹ • Stephen R. Smith, F.R.A.C.S.¹,² • Peter Pockney, F.R.A.C.S.²
Patrick Lim, B.M.¹ • John Attia, F.R.A.C.P.²,³
A Meta-analysis on the Effect of Sham Feeding Following Colectomy: Should Gum Chewing Be Included in Enhanced Recovery After Surgery Protocols?

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Clinical Practice Guidelines for Enhanced Recovery After Colon and Rectal Surgery From the American Society of Colon and Rectal Surgeons and Society of American Gastrointestinal and Endoscopic Surgeons

Based on these considerations, a maintenance infusion of 1.5 - 2 mL/kg/h of balanced crystalloid solution is sufficient to cover the needs derived from salt–water homeostasis during major abdominal surgery\textsuperscript{206,207} while limiting substantial postoperative weight gain (>2.5 kg/d), which is associated with increased morbidity and prolonged hospital stay.\textsuperscript{208}
Clinical Practice Guidelines for Enhanced Recovery After Colon and Rectal Surgery From the American Society of Colon and Rectal Surgeons and Society of American Gastrointestinal and Endoscopic Surgeons

Based on these considerations, a maintenance infusion of 1.5 - 2 mL/kg/h of balanced crystalloid solution is sufficient to cover the needs derived from salt-water homeostasis during surgery.

3. In high-risk patients and in patients undergoing major colorectal surgery associated with significant intravascular losses, the use of goal-directed fluid therapy is recommended. Grade of recommendation: strong recommendation based on moderate-quality evidence, 1B.
A Meta-analysis of the Effectiveness of the Opioid Receptor Antagonist Alvimopan in Reducing Hospital Length of Stay and Time to GI Recovery in Patients Enrolled in a Standardized Accelerated Recovery Program After Abdominal Surgery

P. G. Vaughan-Shaw, M.B.Ch.B. • I. C. Fecher, M.Sc. • S. Harris, M.Sc. • J. S. Knight, M.B.B.S.
A Meta-analysis of the Effectiveness of the Opioid Receptor Antagonist Alvimopan in Reducing Hospital Length of Stay and in Patients Enrolled in a Sta Recovery Program After Ab

P. G. Vaughan-Shaw, M.B.Ch.B. • I. C. Fec
NSQIP: Postoperative Ileus

A Meta-analysis of the Effectiveness of the Opioid Receptor Antagonist Alvimopan in Reducing Hospital Length of Stay and in Patients Enrolled in a Sta Recovery Program After Ab

P. G. Vaughan-Shaw, M.B.Ch.B. • I. C. Fec

Decreases Ileus, May reduce LoS
$600 USD per patient cost!
Not available for us in BC
Enhanced Recovery After Surgery Pathways

- Initially developed and popularized in Denmark by Henrik Kehlet
- Summarized by Lassen & ERAS Study Group, 2009
  - Laparoscopic Surgery
  - Keep patients warm, and reduce peri-operative crystalloid usage
  - Do not place drains
  - Lots of Tylenol (minimize narcotics)
  - Feed ASAP
  - Mobilize effectively and early
Enhanced Recovery After Surgery Pathways

- Does it work?
- 3 Meta-Analyses
  - Varadhan et al. (Nottingham), Eskicioglu et al. (Toronto) & Gouvas et al. (Imperial College)
- 2 days less mean stay
- Fewer peri-operative complications (RR of 0.61)
- $7000/patient cost-savings
The Better Colectomy Project

Association of Evidence-Based Best-Practice Adherence Rates to Outcomes in Colorectal Surgery

Alexander F. Arriaga, MD,*† Robert T. Lancaster, MD, MPH,*‡ William R. Berry, MD, MPH, MPA,* Scott E. Regenbogen, MD, MPH,*§ Stuart R. Lipsitz, ScD,† Haytham M. A. Kaafarani, MD, MPH,*§ Andrew W. Elbardissi, MD, MPH,*† Priya Desai, MPH,*† Stephen J. Ferzoco, MD,¶ Ronald Bleday, MD,† Elizabeth Breen, MD,† William V. Kastrinakis, MD,¶ Marc S. Rubin, MD,¶ and Atul A. Gawande, MD, MPH*†

– Study performed at Brigham Young Womens, Mass General & Faulkner Hospital in Boston
– Identified, by consensus, 15 Key practices, and 22 Best practices
– 370 patients were assessed for compliance
The Better Colectomy Project

Association of Evidence-Based Best-Practice Adherence Rates to Outcomes in Colorectal Surgery

TABLE 1. Description of Evidence-Based Best-Practices Tracked for the Better Colectomy Project*

<table>
<thead>
<tr>
<th>Key Best Practices</th>
<th>Thromboembolism prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection prevention</td>
<td></td>
</tr>
<tr>
<td>1. Removal of intraoperative Foley catheter within 72 hour postoperatively or within 24 hour after removal of intraoperative epidural catheter (if epidural catheter present)</td>
<td>8. Mechanical and chemical prophylaxis for deep venous thrombosis administered/applied before operation</td>
</tr>
<tr>
<td>2. Administration and continuation of appropriate prophylactic antibiotics as recommended by the Surgical Care Improvement Project (SCIP)</td>
<td>9. Mechanical and chemical prophylaxis for deep venous thrombosis administered/applied postoperatively</td>
</tr>
<tr>
<td>3. Intraoperative application of warming device for patients with an intraoperative temperature less than 97.8 °F (36.6°C)</td>
<td>Preoperative assessment and optimization</td>
</tr>
<tr>
<td>4. Removal of central venous catheter unless daily documented reason for continuing</td>
<td>10. Ostomy nurse consulted preoperatively for low anterior resections or planned ostomy</td>
</tr>
<tr>
<td>5. Red blood cell transfusions held for patients with hematocrit &gt;21%, no hemodynamic instability and no history of coronary artery disease</td>
<td>11. Beta blocker therapy given (unless contraindication present) for patients with serum creatinine &gt;2, mg/dL, age &gt;65 yr, current tobacco use, history of angina, history of coronary artery disease, hypertension, congestive heart failure, high cholesterol, stroke, or diabetes</td>
</tr>
<tr>
<td>6. Intraoperative anastomotic testing or fecal diversion for</td>
<td>12. Anti-platelet medications held for at least 7 days preoperatively, unless documented contraindication present</td>
</tr>
<tr>
<td>a. Anastomoses above 5 cm from the anal verge and below the peritoneal reflection, or</td>
<td>13. Warfarin held for at least 4 days preoperatively, unless documented contraindication present</td>
</tr>
<tr>
<td>b. Stapled transanal end-to-end anastomosis, or</td>
<td>14. Cardiology or hospitalist consult obtained if critical preoperative abnormality present (as listed in Supplemental Digital Content 1), unless documented reason for no consultation</td>
</tr>
<tr>
<td>c. Nondverted anastomosis within 5 cm of the anal verge</td>
<td>15. Central venous catheter or 2 peripheral intravenous lines (at least one 18 gauge or larger) placed for cases with estimated blood loss greater than 500 mL.</td>
</tr>
</tbody>
</table>
The Better Colectomy Project

Association of Evidence-Based Best-Practice Adherence Rates to Outcomes in Colorectal Surgery

• Only 14% of patients had perfect adherence to Best Practice
• 11 of 37 practices were adhered to <60% of the time
• 25% of patients had catheters left in too long
• 50% were transfused without good reason
• 59% were not worked up adequately for fever
• 90% had CVL left in too long
• 70% of patients did not comply with DVT guidelines
The Better Colectomy Project

Association of Evidence-Based Best-Practice Adherence Rates to Outcomes in Colorectal Surgery

<table>
<thead>
<tr>
<th>TABLE 5. Association Between Key Processes Missed and the Proportion of Patients With Postoperative Complications*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. Key Processes Missed (Out of 15)</td>
</tr>
<tr>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Percentage of patients with one or more complications</td>
</tr>
</tbody>
</table>

*Mantel-Haenszel $\chi^2$ test for trend, $P = 0.002$.

<table>
<thead>
<tr>
<th>TABLE 7. Multivariate Analysis Testing the Association Between Key Processes Missed and the Proportion of Patients With One or More Complications, Adjusting for Age, and Comorbid Status*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
</tr>
<tr>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>No. key processes missed</td>
</tr>
<tr>
<td>Comorbidity score</td>
</tr>
<tr>
<td>Age $\geq$ 65 yr</td>
</tr>
</tbody>
</table>

*Hospital-to-hospital variation adjusted for as a fixed effect in logistic regression.
Enhanced Recovery After Surgery Pathways

– Do we need it with Laparoscopy?

Laparoscopy in Combination with Fast Track Multimodal Management is the Best Perioperative Strategy in Patients Undergoing Colonic Surgery

A Randomized Clinical Trial (LAFA-study)
Enhanced Recovery After Surgery Pathways
– Do we need it with Laparoscopy?

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<table>
<thead>
<tr>
<th></th>
<th>Laparoscopy and Fast Track (n = 100)</th>
<th>Open and Fast Track (n = 93)</th>
<th>Laparoscopy and Standard care (n = 109)</th>
<th>Open and Standard care (n = 98)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total hospital stay, median (IQR), days</td>
<td>5 (4–8)</td>
<td>7 (5–11)</td>
<td>6 (4.5–9.5)</td>
<td>7 (6–13)</td>
<td>&lt;0.001*†</td>
</tr>
<tr>
<td>Postoperative hospital stay, median (IQR), days</td>
<td>5 (4–7)</td>
<td>6 (4.5–10)</td>
<td>6 (4–8.5)</td>
<td>7 (6–10.5)</td>
<td>&lt;0.001*‡</td>
</tr>
</tbody>
</table>
Enhanced Recovery After Surgery Pathways
– Do we need it with Laparoscopy?

Systematic review and meta-analysis for laparoscopic versus open colon surgery with or without an ERAS programme

W. R. Spanjersberg¹ · J. D. P. van Sambeeck¹ · A. Bremers¹ · C. Rosman² · C. J. H. M. van Laarhoven¹
• Enhanced Recovery After Surgery Pathways

—it gets patients out of hospital faster, but does nothing for complications!
• Enhanced Recovery After Surgery Pathways
  – It gets patients out of hospital faster, but does

Enhanced Recovery Program in Colorectal Surgery:
A Meta-analysis of Randomized Controlled Trials

Massimiliano Greco · Giovanni Capretti ·
Luigi Beretta · Marco Gemma · Nicolò Pecorelli ·
Marco Braga
NSQIP: ERAS and BC

- Enhanced Recovery After Surgery Pathways
  - It gets patients out of hospital faster, but does nothing for complications!

Enhanced Recovery After Surgery Program Implementation in 2 Surgical Populations in an Integrated Health Care Delivery System

3800 patients undergoing elective colorectal surgery
Staggered implementation
Same surgeons, but different institutions
Enhanced Recovery After Surgery Pathways

- It gets patients out of hospital faster, but does nothing for complications!

In the Kaiser-Permanente system, implementation lead to a 32% decrease in complications
# NSQIP: ERAS and BC

<table>
<thead>
<tr>
<th>Active Patient Involvement</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-operative</strong></td>
<td><strong>Intra-operative</strong></td>
</tr>
<tr>
<td>Pre-admission education</td>
<td>Active warming</td>
</tr>
<tr>
<td>Early discharge planning</td>
<td>Opioid-sparing technique</td>
</tr>
<tr>
<td>Reduced fasting duration</td>
<td>Surgical techniques</td>
</tr>
<tr>
<td>Carbohydrate loading</td>
<td>Avoidance of prophylactic NG tubes &amp; drains</td>
</tr>
<tr>
<td>No-selective bowel prep</td>
<td>Goal-directed perioperative fluid management</td>
</tr>
<tr>
<td>Venous thromboembolism prophylaxis</td>
<td></td>
</tr>
<tr>
<td>Antibiotic prophylaxis</td>
<td></td>
</tr>
<tr>
<td>Pre-warming</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Audit of processes &amp; outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multi-disciplinary Team Involvement</td>
</tr>
</tbody>
</table>
NSQIP: ERAS and BC

Sponsor: SSC

Co-Chairs: Anesthesia, Surgery, Nursing/QI

Advisory Panel: Anesthesia, Surgery, Nursing/Admin members from 6 regional HAs

Organizational Partner: BC Patient Safety & Quality Council

Enhanced Recovery Collaborative

- MMH
- UHNBC
- VGH
- RH, LGH
- SPH
- MSJ
- NRGH
- CRH
- RJH, VGH, family physicians
- KGH
- RIH
- KBRH
- RCH
- LMH
- SMH
- ARH, RMH, PAH, family physicians

BC Hip Arthroplasty Collaborative

2 Patient Partners

Anesthesia COP

Surgery COP

Nutrition COP

Nursing COP

BC Patient Safety & Quality Council

FHA

VCH

PHC

Island Health

IH
Collaborative Goals

• 80% compliance on all pathway elements
• 50% reduction in complication rates
• Decrease hospital LOS
• No significant change to readmission rates

Period: November 2015 – December 2015
NSQIP: ERAS and BC

Development of Framework and Change Package (i.e. ERAS protocol)

Recruit & enroll teams

Pre-work

Recruit & enroll teams

Pre-work

LS1 Nov ‘14

AP1

LS2 Apr ‘15

AP2

LS3 Sep ‘15

AP3

Dissemination: outcomes congress (Jan ’16), reports, evaluation

Holding the gains

Spread

Supports: email, website, site visits, monthly reports, monthly team lead meetings, skill-building webinars, Communities of Practice

Based on IHI Breakthrough Series Model
Outcomes: Snapshot

- **Complication Rate**
  - Baseline (n=999): 32%
  - Jan-Oct 2015 (n=920): 22%

- **Readmission Rate**
  - Baseline (n=999): 7%
  - Jan-Oct 2015 (n=920): 7%

- **Median LOS (days)**
  - Baseline (n=999): 7
  - Jan-Oct 2015 (n=920): 5
Complication rate

Target* = 50% reduction from baseline (16% complication rate)

Jan-Oct N=936
Baseline N=999
Median LOS (days)

Jan-Oct N=936
Baseline N=999
No prolonged post-op NPO or NGT use
Foley out by POD2
Solids given by POD2
Mobilized BID POD2
Mobilized POD0 or POD1
Prophylactic antiemetic x 24 hrs
IV d/c POD0 or POD1
Clear fluids started POD0 or POD1
Chewed gum POD0 or POD1
No drains
Multi-modal anti-emetic prophylaxis
Normal temp on arrival to PAR
Thoracic epidural for open cases
Abx redosing (time >4 hours)
Multi-modal pain management
GDT
Blood loss <500ml
VTE prophylaxis
Abx prophylaxis
Two doses of CHO-loading
No bowel prep or MBP + oral abx
Pre-admission counseling
Pathway Adherence Changes (%) January-October 2015 n=936

October Cumulative  Baseline
Resources for Spread and Sustainability

**Network of Teams**
- physicians, nurses, admin, allied health

- Data Set & Tools
- Website of Resources
- Webinars
- Clinical Guidance Docs
- Patient Education Videos
- process & outcome measures
- order sets
- patient education
- staff education references
- data set & tools
- presentations
- patient story video
- applicable to many surgeries
- English, Cantonese, Mandarin, Punjabi

- Pathway basics
- Process Mapping
- Train-the-trainer
- Post-op Pain
- Run Charts
- Mechanical Bowel Prep
- Carbohydrate-Loading
- Goal-directed Fluid Therapy
- Opioid-Sparing Technique
ERAS: What’s new in BC and Providence?

• Nutrition
  – Pre-operative assessment for at risk patients
    • Rapid weight loss and morbidly obese patients
  – Carbohydrate loading
  – Early Feeding
    • Since January 2017, patients get a transitional diet and advised to eat as per their appetite
      – Solids, Clears and Full
ERAS: What’s new in BC and Providence?

• Intra-operative
  – Intravenous Fluids (Goal directed)
    • Fluid monitoring techniques
    • Fluids on a pump
  – Redosing of Antibiotics at 4 hours
ERAS: What’s new in BC and Providence?

• Royal Columbian Hospital
  – Anemia treatment with Iron infusions

• Vancouver Coastal Health and Providence Health
  – Geriatric Assessment of frail and at risk patients > 75
ERAS: What’s new in BC and Providence?

- Prehabilitation / Pre-operative Optimization Trial
  - Exercise Counseling
  - Dietary Counseling
  - Relaxation/Anxiety Treatment (Music Therapy)
2006: New negotiated Physician Master Agreement
- Hard dollars committed to Facilities based Quality Improvement and Physician Engagement
The QI Landscape in BC

• Facility Based Physician Engagement
• Quality and Innovation Projects
  – ERAS Collaborative
  – Hip Fracture Redesign
• Regional Quality Improvement
  – QI Education
  – Regional QI Networks
  – Support for time spent
The QI Landscape in BC

• Costs
  – Process Changes
    • Physician Engagement
    • Physician Time
    • Change to work of Nursing
      – CNS
      – CNLs and CNEs
Conclusions

• Complications in Colorectal Cancer Surgery come at a cost
  – System, patients and oncological
• Complications can be measured and potentially reduced
• A care pathway, like ERAS, definitively reduces complications
• There are opportunities available to you for assessment and implementation of quality improvement
Doctors and scientists are now being asked to accept a new understanding of what great medicine requires. It is not just the focus of an individual artisan-specialist, however skilled and caring. And it is not just the discovery of a new drug or operation, however effective it may seem in an isolated trial. Great medicine requires the innovation of entire packages of care—with medicines and technologies and clinicians designed to fit together seamlessly, monitored carefully, adjusted perpetually, and shown to produce ever better service and results for people at the lowest possible cost for society.

- Gawande, Stanford Commencement, 2010
NSQIP: Anastomotic Leaks

- Prevention is better than cure
• Oral Antibiotics

Systematic review of perioperative selective decontamination of the digestive tract in elective gastrointestinal surgery

D. Roos¹, L. M. Dijksman², J. G. Tijssen³, D. J. Gouma⁴, M. F. Gerhards⁵ and H. M. Oudemans-van Straaten⁶

Oral Antibiotics decrease Anastomotic Leak rates
NSQIP: Anastomotic Leaks

• Oral Antibiotics + Mechanical Bowel Prep

Combined Preoperative Mechanical Bowel Preparation With Oral Antibiotics Significantly Reduces Surgical Site Infection, Anastomotic Leak, and Ileus After Colorectal Surgery

Ravi Pokala Kiran, MBBS, MS, FRCS, FACS, MSc (EBM), FASCRS,*† Alice C. A. Murray, BSc, MBBS, MRCS,*
Cody Chiuza, PhD,† David Estrada, MD,* and Kenneth Forde, MD*

Combined Mechanical and Oral Antibiotic Bowel Preparation Reduces Incisional Surgical Site Infection and Anastomotic Leak Rates After Elective Colorectal Resection

An Analysis of Colectomy-Targeted ACS NSQIP

John E. Scarborough, MD, Christopher R. Mantyh, MD, PhD, Zhifei Sun, MD, and John Migaly, MD
Combined Preoperative Mechanical Bowel Preparation With Oral Antibiotics Significantly Reduces Surgical Site Infection, Anastomotic Leak, and Ileus After Colorectal Surgery

Ravi Pokala Kiran,*, MD, FRCSEd, FRCS, FCS Surg, FRCPath, BSc, MBBS, MRCS,* FFR

Combined Preoperative Mechanical Bowel Preparation Reduces Incisional Surgical Site Infection and Anastomotic Leak Rates After Elective Colorectal Resection

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John E. Scarborough, MD, Christopher R. Mantyh, MD, PhD, Zhifei Sun, MD, and John Migaly, MD

Oral Antibiotics with Mechanical Bowel Preparation decreases Anastomotic Leak rates!
NSQIP: Anastomotic Leaks

• Routine Diversion?

Decreased Anastomotic Leak (RR 0.33)
Less Return to OR (RR 0.23)

Divert all high risk colorectal anastomoses
NSQIP: Anastomotic Leaks

- Fluorescence Imaging
  - Ensure anastomotic sites are well vascularized
NSQIP: Anastomotic Leaks

- Fluorescence Imaging

Perfusion Assessment in Laparoscopic Left-Sided/Anterior Resection (PILLAR II): A Multi-Institutional Study

- 147 Patients
- Resection margin changed in 10 patients
- 4 leaks (2 clinical, 2 radiological)
PILLAR III

- Randomized, controlled, parallel, multicenter study
- Determine the reduction in anastomotic leak rate LAR using PINPOINT or SPY Elite compared to standard surgical practice alone
Inclusion criteria

• Open or minimally invasive low anterior, coloanal resection for a rectal or rectosigmoid neoplasm

• Planned anastomosis 10 cm or less from the anal verge
Subject Randomization
Sample size calculation: 550 patients

Stratify by Site
Assess for eligibility
Randomize

Neo-adjuvant therapy
Non Neo-adjuvant therapy

Group A: Perfusion
Group B: Standard of Care

PILLAR III Clinical Study Protocol PP PLR 03
Cleveland Clinic Florida
PILLAR III
Primary Endpoints

- To demonstrate an improvement in post-operative anastomotic leak rate in low anterior resection procedures where colon and rectal tissue perfusion is evaluated
  - PINPOINT or SPY vs standard surgical practice alone
Phase II European trial
PINPOINT in colorectal surgery

• Multi-centered, phase II prospective trial
• Geneva/Oxford/Dublin
• 375 elective colorectal resections
• Indications
  – Colorectal cancer - 65%
  – Diverticular disease - 18%
  – Crohn’s disease - 9%
  – Ulcerative colitis – 3%
  – Other – 5%

Ris et al. In press
Phase II European trial
PINPOINT in colorectal surgery

Type of surgery

Ris et al. In press
Phase II European trial
PINPOINT in colorectal surgery

- Technique
  - Laparoscopy – 90%
  - Open – 10%
  - Conversion – 6%
- PINPOINT possible in 100% of cases
- Added procedure time
  - 4 min (0.2-20 min)
  - 2 assessments
- Time for ICG to reach anastomosis: 30 sec.(10-107s)

Ris et al. In press
Phase II European trial
PINPOINT in colorectal surgery

- Alteration in surgical resection margin: 6% (24 patients)
  - 18 patients at first image acquisition

- Change in resection margin: 0.5-2.0cm

- 6 patients required 2\textsuperscript{nd} injection of ICG
  - 5 patients – no diverting stoma due to perfusion

- No anastomotic leaks in patients with altered resection margin

\textit{Ris et al. In press}
Phase II European trial
PINPOINT in colorectal surgery

- Anastomotic leak rate – 2.4% (9/375)
- Stratified data
  - 3 – Right hemicolectomy
    - Treated with ileostomy
  - 3 - (2) High anterior resection and (1) Hartman reversal
    - Treated with creation of end-colostomy after anastomosis takedown
  - 3 – Low anterior resection
    - Treated with EUA and transanal drainage leading to salvage

Ris et al. In press
Phase II European trial
PINPOINT in colorectal surgery

- No ICG allergic reaction
- No Mortality
- Complications
  - Grade III-IV complication 8%
  - Grade II complication: 9%
  - No complication: 73%
- Re-operation 14

Ris et al. In press
NSQIP: Anastomotic Leaks

• Fluorescence Imaging
  – May have some potential