Study Title: Wound Management in Emergency Colorectal Surgery: To Close or Not to Close?

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Background and significance: Surgical site infections (SSIs) pose a significant burden on both patients and healthcare systems, as the most common hospital-acquired infection in surgical patients and accounting for more than 1.6 billion in direct costs.[1,2] Due to these factors, SSIs serve as an important quality measure, with reporting required and reimbursement dependent on these outcomes.[3] National guidelines, such as the Surgical Care Improvement Program (SCIP), have been developed with the aim to provide a bundled intervention to significantly reduce SSIs and improve the quality of care of surgical patients.[4]

SCIP measures focus on mitigating well known risk factors of surgical site infection, such as contamination, temperature regulation, and glucose control.[5] However, many risk factors cannot be modified, specifically patient characteristics and indication for procedures. Colorectal surgery carries a higher risk of SSI, with reported SSI incidences ranging from 5-30%.[1,6] More importantly, indication for operation can further influence risk of SSI, as emergent procedures carry increased rates of contamination, metabolic derangements, hemodynamic changes, and longer operative times.[7,8,9] Previous studies have suggested that management of skin closure according to these risk factors can decrease rate of SSIs.[8,10,11,12] However, the clinical and economic burden of these variable wound management strategies remains largely unexplored. Acker and colleagues performed a retrospective review of the clinical and economic impact of wound management strategies in patients who received a laparotomy for traumatic injuries. They found that the patients with colonic injuries that were managed with open skin incisions, as compared to those with closed incisions, had significantly longer hospital length of stay, greater average number of post-operative visits and longer time to last outpatient follow up.[13]

It is well known that certain risks factors, including contaminated wounds, emergent procedures, and colorectal surgery, carry higher risk of surgical site infection. Consequentially, it has become common practice to manage the skin incision differently in these circumstances. Some advocate open surgical incisions, with the possibility of delayed primary closure, while others continue to close skin incisions with close follow up, in hopes to reduce the clinical burden on the patient. However, the question of the clinical impact of wound management strategy in emergent colorectal surgery patients remains unanswered. Most of the literature has included trauma patients or patients receiving elective operations. What still remains unanswered is the question: What is the best method of wound management in emergency, nontraumatic, colorectal surgery patients, not only for reducing the incidence of surgical site infection, but improving length of stay, follow up and other quality metrics relevant to both the patient and the health system? We hypothesize that there is increased length of stay, but no significant difference in other quality metrics among patients with varying wound management techniques. This study attempts to answer this question through evaluation of 3 specific aims.

Specific Aims of MCT:

Primary Aim: To determine the clinical impact of wound management techniques on hospital length of stay and mortality in emergency colorectal surgery.

Secondary Aims:

1. To describe the variability of practice of wound management techniques in emergency colorectal surgery.
2. To describe the relationship between wound management techniques and other emergency colorectal surgery quality measures: surgical site infection and 30 day readmissions.

Experimental Design/Methods:

Design: Prospective observational

Inclusion Criteria: All patients undergoing an urgent or emergent surgical intervention for colorectal pathology will be enrolled.

Exclusion Criteria: Patients who are prisoners, pregnant, less than 18 years of age, undergoing surgical intervention for traumatic mechanism, receive an elective surgical intervention, mortality within 5 days of final laparotomy.

Outcome Measures:

Primary Outcome: Length of stay, time to last follow up, mortality

Secondary Outcome: Incidence of superficial or deep incisional surgical site infection, or organ space infection as defined by the Centers for Disease Control and Prevention (CDC). 30 day readmission after surgery. Variability in practice of wound management in emergency colorectal surgery.

Variables:

Demographics

- Age
- Sex
- Race
- Ethnicity
- BMI

History

- Diabetes Mellitus
- Liver disease
- Chronic kidney disease
- Congestive heart failure
- Myocardial infarction/ h/o CABG
- Cancer
- Chemotherapy
- Chronic steroid use
- AIDS
- Previous abdominal surgery
- COPD

- Rheumatic or connective tissue disease
- Chronic anticoagulation/dual antiplatelet therapy
- Current smoking
- Charlson Comorbidity Index

Pre-op

- Heart rate
- Blood pressure
- Temperature
- GCS
- Intubated
- Vasopressor use
- WBC
- Hgb
- Hct
- Plat
- pH
- Base excess
- PT
- PTT
- INR
- Lactate
- Creatinine
- Bilirubin
- Albumin
- ASA PS Classification

Intra-op

- Indication for operation, AAST grade
- Antibiotic prophylaxis within 1 hour of incision
- Operative time
- Intra-operative colloids
- Intra-operative crystalloids
- Intra-operative vasopressors
- Recorded intra-op temp <36
- Estimate blood loss
- Procedure type
    - Right colon
    - Left colon
    - Rectum
- Creation of stoma
- Wound management technique
    - Skin closed
    - Skin loosely closed
    - Skin open
- Negative Pressure Wound Therapy initiated within 24 hours of index operation

- Wound classification

Post-operative

- ICU LOS
- Hospital LOS
- Time to last follow-up
- Post-op steroids use
- Post-op vasopressor requirement
- Surgical Site Infection
    - Classification (superficial, deep, organ space)
    - Number of post-op days to infection
    - Treatment modality (antibiotics, wound management)
- Unplanned reoperation/intervention
- Delayed Primary Closure (DPC)
    - Days to DPC
- ARDS
- AKI
- PE
- Stroke
- MI
- Enteric fistula
- Disposition
- If mortality, cause of death.
- 30 day readmission

Data Collection and Statistical Analysis: Standardized data will be collected prospectively via a data collection sheet, and deidentified data will captured using the Research Electronic Data Capture (REDCap) system. Resulting data will be exported for descriptive and inferectial analysis in SPSS Statistics software package (IBM©). Univariate comparisons of patient characteristics and outcomes across wound management techniques will be conducted using one-way analysis of variance (ANOVA) and Chi-squared tests, as indicated. All post-hoc comparisons of specific techniques will be performed using Bonferroni correction. Demographics, history, pre-op, and intra-op details with differences across groups that are significant at $p < 0.20$ will be considered for inclusion in multivariate regression models to adjust for these factors. Multivariate logistic regression will then be performed to assess differences in dichotomous outcome variables between wound closure techniques after adjusting for potential confounding factors. Cox proportional hazard regression will be used to evaluate differences in length of stay. Data will be reported as adjusted odds ratios and hazard ratios with 95% confidence intervals, with a statistical significance set at a $p<0.05$. Variability in wound management techniques will be assessed using the Chi-square test to examine differences in the proportion of total surgeries using each technique and differences across subgroups.

Consent Procedures: This is a prospective observational study, aimed at prospectively recording data on patients who are managed according to institutional management protocols. Therefore, a waiver of informed consent is requested. All data will be recorded an captured via REDCap devoid of patient identifiers.

Risk/Benefit Analysis: The clinical burden of wound management strategies beyond surgical site infection in emergent colorectal surgery patients is largely unknown. Determine the optimal wound management technique to lessen the burden of patients, and improve quality of care would provide significant benefit to this patient population.

References:

1. de Lissovoy G, Fraeman K, Hutchins V, Murphy D, Song D, Vaughn BB. Surgical site infection: incidence and impact on hospital utilization and treatment costs. Am J Infect Control. 2009 Jun;37(5):387-397. doi: 10.1016/j.ajic.2008.12.010. Epub 2009 Apr 23. PMID: 19398246.
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4. Munday GS, Deveaux P, Roberts H, Fry DE, Polk HC. Impact of implementation of the Surgical Care Improvement Project and future strategies for improving quality in surgery. Am J Surg. 2014 Nov;208(5):835-840. doi: 10.1016/j.amjsurg.2014.05.005. Epub 2014 Jul 1. PMID: 25113797.
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8. Seamon MJ, Smith BP, Capano-Wehrle L, Fakhro A, Fox N, Goldberg M, Martin NM, Pathak AS, Ross SE. Skin closure after trauma laparotomy in high-risk patients: opening opportunities for improvement. J Trauma Acute Care Surg. 2013 Feb;74(2):433-9; discussion 439-40. doi: 10.1097/TA.0b013e31827e2589. Erratum in: J Trauma Acute Care Surg. 2013 Jul;75(1):185. PMID: 23354235.
9. Cheng H, Chen BP, Soleas IM, Ferko NC, Cameron CG, Hinoul P. Prolonged Operative Duration Increases Risk of Surgical Site Infections: A Systematic Review. Surg Infect

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Form "EAST Multicenter Study Proposal"
Details #109 (submitted 10/01/2020)

Study Title	Wound Management in Emergency Colorectal Surgery: To Close or Not to Close?
Primary investigator / Senior researcher	Cristina Barbosa Feather, MD, MHS
Email of Primary investigator / Senior researcher	cfeather@aahs.org
Co-primary investigator	J. Robert Klune, MD, MBA
Are you a current member of EAST?	Yes
If you selected "No" above please identify a Sponsor that is an active EAST member:	
My Multicenter Study proposal is...	Prospective

Use this area to briefly (1-2 paragraphs only) outline the burden of the problem to be examined

Surgical site infections (SSIs) pose a significant burden on both patients and healthcare systems, as the most common hospital-acquired infection in surgical patients and accounting for more than 1.6 billion in direct costs.1,2 Due to these factors, SSIs serve as an important quality measure, with reporting required and reimbursement dependent on these outcomes.3 National guidelines, such as the Surgical Care Improvement Program (SCIP), have been developed with the aim to provide a bundled intervention to significantly reduce SSIs and improve the quality of care of surgical patients.4

SCIP measures focus on mitigating well known risk factors of surgical site infection, such as contamination, temperature regulation, and glucose control.5 However, many risk factors cannot be modified, specifically patient characteristics and indication for procedures. Colorectal surgery carries a higher risk of SSI, with reported SSI incidences ranging from 5-30%.1,6 More importantly, indication for operation can further influence risk of SSI, as emergent procedures carry increased rates of contamination, metabolic derangements, hemodynamic changes, and longer operative times.7,8,9 Previous studies have suggested that management of skin closure according to these risk factors can decrease rate of SSIs.8,10,11,12 However, the clinical and economic burden of these variable wound management strategies remains largely unexplored. Acker and colleagues performed a retrospective review of the clinical and economic impact of wound management strategies in patients who received a laparotomy for traumatic injuries. They found that the patients with colonic injuries that were managed with open skin incisions, as compared to those with closed incisions, had significantly longer hospital length of stay, greater average number of post-operative visits and longer time to last outpatient follow up.13

It is well known that certain risks factors, including contaminated wounds, emergent procedures, and colorectal surgery, carry higher risk of surgical site infection. Consequentially, it has become common practice to manage the skin incision differently in these circumstances. Some advocate open surgical incisions, with the possibility of delayed primary closure, while others continue to close skin incisions with close follow up, in hopes to reduce the clinical burden on the patient. However, the question of the clinical impact of wound management strategy in emergent colorectal surgery patients remains unanswered. Most of the literature has included trauma patients or patients receiving elective operations. What still remains unanswered is the question: What is the best method of wound management in emergency colorectal surgery patients, not only for reducing the incidence of surgical site infection, but improving length of stay, follow up and other quality metrics relevant to both the patient and the health system? This study attempts to answer this question through evaluation of 3 specific aims.

Primary aim

To determine the clinical impact of wound management techniques on hospital length of stay and mortality in emergency colorectal surgery.

Secondary aims

1.To describe the variability of practice of wound management techniques in emergency colorectal surgery.

2.To describe the relationship between wound management techniques and other emergency colorectal surgery quality measures: surgical site infection and 30 day readmissions.

Inclusion Criteria	All patients undergoing an urgent or emergent surgical intervention for colorectal pathology will be enrolled.
Exclusion Criteria	Patients who are prisoners, pregnant, less than 18 years of age, receive an elective surgical intervention, mortality within 5 days of final laparotomy.
Therapeutic Interventions	Prospective observational study only. Patients will be managed according to surgeon's discretion.
Primary Outcome	Length of stay, time to last follow up, mortality
Secondary Outcomes	Incidence of superficial or deep incisional surgical site infection, or organ space infection as defined by the Centers for Disease Control and Prevention (CDC). 30 day readmission after surgery. Variability in practice of wound management in emergency colorectal surgery.

List specific variables to be collected & analyzed

Demographics

•Age

•Sex

•Race

•Ethnicity

•BMI

History

•Diabetes Mellitus

•Liver disease

•Chronic kidney disease

•Congestive heart failure

•Myocardial infarction/ h/o CABG

•Cancer

•Chemotherapy

•Chronic steroid use

•AIDS

•Previous abdominal surgery

•COPD

•Rheumatic or connective tissue disease

•Chronic anticoagulation/dual antiplatelet therapy

•Current smoking

•Charlson Comorbidity Index

Pre-op

•Heart rate

•Blood pressure

•Temperature

•GCS

•Intubated

•Vasopressor use

•WBC

•Hgb

•Hct

•Plat

•pH

•Base excess

•PT

•PTT

•INR

•Lactate

•Creatinine

•Bilirubin

•Albumin

•ASA PS Classification

Intra-op

•Indication for operation, AAST grade

•Antibiotic prophylaxis within 1 hour of incision

•Operative time

•Intra-operative colloids

•Intra-operative crystalloids

•Intra-operative vasopressors

•Recorded intra-op temp <36

•Estimate blood loss

•Procedure type

oRight colon

oLeft colon

oRectum

•Creation of stoma

•Wound management technique

oSkin closed

oSkin loosely closed

oSkin open

•Negative Pressure Wound Therapy initiated within 24 hours of index operation

•Wound classification

Post-operative

•ICU LOS

•Hospital LOS

•Time to last follow-up

•Post-op steroids use

•Post-op vasopressor requirement

•Surgical Site Infection

oClassification (superficial, deep, organ space)

oNumber of post-op days to infection

oTreatment modality (antibiotics, wound management)

•Unplanned re-operation/intervention

•Delayed Primary Closure (DPC)

oDays to DPC

•ARDS

•AKI

•PE

•Stroke

•MI

•Enteric fistula

•Disposition

•If mortality, cause of death.

•30 day readmission

Outline the data collection plan and statistical analysis plan succinctly

Standardized data will be collected prospectively via a data collection sheet, and de-identified data will captured using the Research Electronic Data Capture (REDCap) system. Resulting data will be exported for descriptive and inferential analysis in SPSS Statistics software package (IBM?). Univariate comparisons of patient characteristics and outcomes across wound management techniques will be conducted using one-way analysis of variance (ANOVA) and Chi-squared tests, as indicated. All post-hoc comparisons of specific techniques will be performed using Bonferroni correction. Demographics, history, pre-op, and intra-op details with differences across groups that are significant at $p < 0.20$ will be considered for inclusion in multivariate regression models to adjust for these factors. Multivariate logistic regression will then be performed to assess differences in dichotomous outcome variables between wound closure techniques after adjusting for potential confounding factors. Cox proportional hazard regression will be used to evaluate differences in length of stay. Data will be reported as adjusted odds ratios and hazard ratios with 95% confidence intervals, with a statistical significance set at a $p<0.05$. Variability in wound management techniques will be assessed using the Chi-square test to examine differences in the proportion of total surgeries using each technique and differences across subgroups.

Outline consent procedures here, if applicable

This is a prospective observational study, aimed at prospectively recording data on patients who are managed according to institutional management protocols. Therefore, a waiver of informed consent is requested. All data will be recorded an captured via REDCap devoid of patient identifiers.

Succinctly outline a risk/benefit analysis

The clinical burden of wound management strategies beyond surgical site infection in emergent colorectal surgery patients is largely unknown. Determine the optimal wound management technique to lessen the burden of patients, and improve quality of care would provide significant benefit to this patient population.

Include a brief listing of key references

1.de Lissovoy G, Fraeman K, Hutchins V, Murphy D, Song D, Vaughn BB. Surgical site infection: incidence and impact on hospital utilization and treatment costs. Am J Infect Control. 2009 Jun;37(5):387-397. doi: 10.1016/j.ajic.2008.12.010. Epub 2009 Apr 23. PMID: 19398246.

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