

# Care Bundle in Reducing Surgical Site Infection in Lower Gastrointestinal Surgeries: A Retrospective Analysis at a Tertiary Care Hospital, Ernakulam, Kerala

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## ABSTRACT

**Introduction:** Surgical Site Infections (SSI) are serious postoperative complications with significant impact on morbidity and mortality ranging from wound discharge associated with superficial skin infection to life-threatening conditions such as severe sepsis. In developed countries, guidelines for preventing SSI have been widely adopted. These evidence-based measures to prevent SSI are usually called 'care bundles', and multiple studies have confirmed that bundle compliance is associated with a significant reduction in the risk of SSI.

**Aim:** To evaluate the efficacy of bundle interventions in reducing SSI rate and readmission rate due to SSI.

**Materials and Methods:** Present study was a retrospective, observational, case-control study conducted on records of 82 patients who underwent primary surgery for elective open lower gastrointestinal surgeries between January 2019-February 2020. Patients were divided into care bundle group (cases) from the concerned unit and non care bundle group (controls) from the other units of the General Surgery Department. Clinical data was obtained from the Medical Records Department and case sheets retrieved. The primary outcome was to measure the rate

of superficial SSIs. Secondary outcomes included deep and organ space SSIs, wound dehiscence, postoperative sepsis, length of stay & 30-day readmission was measured. Statistical analysis were performed with Statistical Package for Social Sciences (SPSS) version 20.0.

**Results:** In present study, total 82 patients undergoing lower gastrointestinal surgeries were included. SSI was noted in 10% from cases group and 21.4% from control group. Significant SSIs (p-value <0.001) were noted in control group. Patients with SSIs from cases group required significantly less treatment with antibiotics and daily dressing (p-value <0.001). One patient from control group required re-exploratory laparotomy for organ space SSI. In surgeries lasting for more than 120 minutes, SSI in cases group patients (5%) were less than control group (14%) and difference was statistically significant. (p-value=0.016). About 9.5% of control group patients required readmission.

**Conclusion:** Multimodal bundle approach for SSI prevention is an innovative way to reduce SSI burden among patients undergoing lower gastrointestinal surgeries. Simple preoperative, operative & postoperative interventions can bring down SSI incidence significantly.

**Keywords:** Bundle intervention, Infection prevention, Nosocomial infection, Organ space surgical site infection, Wound dehiscence

## INTRODUCTION

The SSIs are defined as a wound infection that occurs within 30 days of an operative procedure and the infection is thought to be secondary to surgery [1].

SSIs are serious postoperative complications with significant impact on morbidity and mortality ranging from wound discharge associated with superficial skin infection to life-threatening conditions such as severe sepsis. SSIs are important factor for an increased economic burden to healthcare systems, due to additional postoperative hospital stay, treatment and readmission [2].

A systematic review and meta-analysis [3] noted that, the combined prevalence of SSI in elective clean and clean contaminated surgeries was 6%. While prevalence of SSI in several different surgical disciplines (neurosurgery, cardiovascular, orthopaedic, abdominal wall, and others) ranged from 4% to 6%. Common risk factors for SSIs are presence of premorbid conditions such as diabetes and hypertension in patient, type of surgical intervention, whether elective or emergency surgery, duration of surgery, timing and choice of antimicrobial prophylaxis, quality of postoperative surgical care, the American Society of Anaesthesiologists (ASA) score, wound contamination class, sterilisation procedures of instruments, etc., [4].

Identifying the gaps in current infection prevention practices will help to minimise morbidity, mortality and healthcare costs associated with SSI, as it continues to pose challenges in patient management, detailed and specific identification of the factors which may place patient at greater risk of SSI [5]. In developed countries, guidelines for preventing SSIs have been widely adopted [5]. These evidence-based measures to prevent SSI are usually called 'care bundles', and few studies have confirmed that bundle compliance is associated with a significant reduction in the risk of an SSI [3-5].

Reduction of SSI risk by an average of 40.2% was observed in a meta-analysis that has shown, preventive measures in colorectal surgery when used in the form of bundles (i.e., sets of usually 3-5 measures implemented in a consistent and combined fashion [6,7]. In present study, we prepared a care bundle & evaluated role of 'Bundle Intervention' in reducing SSIs among patients undergoing lower gastrointestinal surgeries at our tertiary care hospital. The primary outcome measures the rate of superficial SSI. Secondary outcomes included deep and organ space SSIs, wound dehiscence, postoperative sepsis, length of stay & 30-day readmission.

## MATERIALS AND METHODS

Present study was a retrospective, observational, case-control study conducted at Department of General Surgery, Government Medical

College, Ernakulam. Institutional Ethical Committee approval was taken (No.IEC-34/2020). The clinical data was collected retrospectively from records of all patients who underwent primary surgery for elective open lower gastrointestinal surgeries between January 2019-February 2020 (14 months).

**Inclusion criteria:** All patients between 18 and 90 years of age of either gender who underwent elective open lower gastrointestinal surgeries were included.

**Exclusion criteria:** All the laparoscopic minimal invasive abdominal surgeries, emergency operated cases, patients with history of previous abdominal surgeries were excluded from the study.

Baseline patient information were retrieved to include date of birth, age, sex, height, weight, relevant medical history, history of previous surgery, details regarding the preoperative morbid status, co-morbidities and clinical parameters. Details of the postoperative patients with wound discharge in whom microbiological evaluation was done (culture and sensitivity) and antibiotics prescribed accordingly were noted. Patients were divided into care bundle group (cases) from the concerned unit (unit 1) and non care bundle group (control) from the other units (unit 2 &3) of the General Surgery Department. Clinical data was obtained from the medical records department and case sheets retrieved.

A set of interventions that, when used together is called as care bundle which significantly improve patient outcomes. Care bundle is a set of three to five evidence-based practices and interventions supported by research, that when used together cause significant improvement in patient outcomes [8]. All the patients in the care bundle group from the concerned unit received following measures:

**1. Preoperative:** Chlorhexidine shower, Mechanical bowel preparation, Standardisation of preparation of surgical field with chlorhexidine.

**2. Operative:** Fascial wound protector, dedicated wound closure tray, glove change before fascial closure, maintenance of euglycaemia, maintenance of normothermia during surgery and in the early postoperative period.

**3. Postoperative:** Removal of sterile dressing within 48 hour, daily washings of incisions with chlorhexidine.

The non care or control group subjects were managed conservatively using systematic approach of preoperative care, best practices across the phases of perioperative and postoperative care.

Data was collected retrospectively from case sheets with regards to preoperative, intraoperative and postoperative details. Postoperative discharge card & follow-up details in SSI patients were noted from records. Surgical wounds were labelled as clean, clean contaminated & contaminated as per Centers for Disease Control and Prevention/National Health Care Safety Network (CDC/NHSN) surveillance definitions [9].

The primary outcome was to measure the rate of superficial SSIs. Secondary outcomes included deep and organ space SSIs, wound dehiscence, postoperative sepsis, length of hospital stay & 30-day readmission.

## STATISTICAL ANALYSIS

All analysis were performed in IBM SPSS for Windows, version 20.0. In statistical analysis, continuous variables were presented as mean, standard deviation, minimum and maximum values. Categorical variables will be expressed as frequency and percentages. To find the association between categorical variables, Pearson's chi-squared test/Fisher's-exact test was used. To find the mean comparison between continuous variables by Independent samples t-test, p-value less than 0.05 was considered as statistically significant.

## RESULTS

In present study, total 82 patients undergoing lower gastrointestinal surgeries were included. In both groups, male patients were more than female patients. Hypertension was most common co-morbidity in both groups, followed by diabetes, chronic obstructive pulmonary disease, dyslipidaemia & coronary artery disease. All cases and control group received prophylactic antibiotics (100%) [Table/Fig-1].

| Patient parameters                   |                                       | Care bundle group (n=40) | Non care bundle group (n=42) | p-value       |
|--------------------------------------|---------------------------------------|--------------------------|------------------------------|---------------|
| Age (in years)                       | 18-30                                 | 14 (35%)                 | 16 (38.09 %)                 |               |
|                                      | 31-40                                 | 5 (12.5%)                | 5 (11.90 %)                  |               |
|                                      | 41-50                                 | 6 (15%)                  | 3 (7.14 %)                   |               |
|                                      | 51-60                                 | 6 (15%)                  | 9 (21.42%)                   |               |
|                                      | 61-70                                 | 3 (7.5%)                 | 5 (11.90 %)                  |               |
|                                      | 71-80                                 | 3 (7.5%)                 | 4 (9.52%)                    |               |
|                                      | >80                                   | 3 (7.5%)                 | 0                            |               |
| Average age (in years)               |                                       | 44.6±8.2                 | 41.95±9.5                    |               |
| Gender                               | Male                                  | 22                       | 30                           |               |
|                                      | Female                                | 18                       | 12                           |               |
| Male: Female                         |                                       | 1.3:1                    | 2.5:1                        |               |
| Body mass index (kg/m <sup>2</sup> ) |                                       | 23.4±4.5                 | 24.1±3.8                     |               |
| Co-morbidities                       | Diabetes                              | 8 (20%)                  | 8 (19.04%)                   | 0.89          |
|                                      | Hypertension                          | 10 (25%)                 | 11 (26.19%)                  | 0.72          |
|                                      | Coronary artery disease               | 4 (10%)                  | 4 (9.52%)                    | -             |
|                                      | Chronic obstructive pulmonary disease | 6 (15%)                  | 3 (7.14%)                    | 0.082         |
|                                      | Dyslipidaemia                         | 1 (2.5%)                 | 3 (7.14%)                    | 0.34          |
|                                      | Smoking                               | 7 (17.5%)                | 18 (42.85%)                  | <b>0.032*</b> |
|                                      | H/o previous surgery                  | 9 (22.5%)                | 6 (14.28%)                   | 0.082         |
| ASA status                           | I                                     | 8 (20%)                  | 9 (21.42%)                   |               |
|                                      | II                                    | 21 (52.5%)               | 20 (47.61%)                  |               |
|                                      | III or more                           | 11 (27.5%)               | 13 (45.23%)                  |               |
| Received prophylactic antibiotics    |                                       | 40 (100 %)               | 42 (100%)                    |               |

**[Table/Fig-1]:** Distribution of baseline and clinical characteristics of patients (n=82). (Pearson's chi-squared test; \* p-value less than 0.05 was considered as statistically significant); H/o: History of

In present study, open appendectomy was most common procedure. Most common surgical approach was from midline vertical incision (60%). Most patients stayed for less than 5 days, while mean duration of hospitalisation was 8.2±3.7 days in case group & 9.3±4.1 days in control group which is not statistically significant. About 9.5% from control group required readmission for SSI [Table/Fig-2].

SSI was noted in 10% from cases group & 21.4% from control group. Significant SSIs were noted in control group [Table/Fig-3]. Patients with SSIs from cases group required significantly less treatment with antibiotics and daily dressing [Table/Fig-4]. Wound discharge from each SSI patient was sent for microbiological evaluation (culture and sensitivity). Antibiotics were prescribed accordingly [Table/Fig-5]. In surgeries lasting for more than 120 minutes, SSI in cases group patients (5%) were less than control group (14%) & difference was statistically significant [Table/Fig-6]. Antibiotics and daily dressing were showed very highly statistically significant with p-value <0.001 and resuturing and exploratory laparotomy were not showed any significant with p-value >0.05 as shown in [Table/Fig-4].

## DISCUSSION

SSIs are reported as third most common nosocomial infection and approximately 25% of all nosocomial infections [10].

| Variables                                      | Care bundle group (n=40) | Non care bundle group (n=42) | Odds ratio (95% C.I.) |
|--|--------------------------|------------------------------|-----------------------|
| <b>Type of surgery</b>                         |                          |                              |                       |
| Open appendectomy                              | 17 (42.5%)               | 19 (45.2%)                   | 1.12 (0.14-8.82)      |
| Exploratory laparotomy                         | 6 (15%)                  | 9 (21.4%)                    | 1.50 (0.16-13.7)      |
| Right hemicolectomy                            | 1 (2.5%)                 | 3 (7.1%)                     | 3.00 (0.15-59.8)      |
| Midline laparotomy                             | 2 (5%)                   | 2 (4.8%)                     | Ref.                  |
| Hartmann's operation                           | 2 (5%)                   | 1 (2.4%)                     | 0.50 (0.02-11.1)      |
| Low anterior resection                         | 0                        | 1 (2.4%)                     | -                     |
| Abdominal rectopexy                            | 3 (7.5%)                 | 1 (2.4%)                     | 0.33 (0.20-6.65)      |
| Palliative feeding jejunostomy                 | 4 (10%)                  | 1 (2.4%)                     | 0.25 (0.10-4.73)      |
| Laparotomy and hernia repair                   | 2 (5%)                   | 1 (2.4%)                     | 0.50 (0.02-11.1)      |
| APR  | 2 (5%)                   | 1 (2.4%)                     | 0.50 (0.02-11.1)      |
| Exploratory laparotomy and BR anastomosis      | 0                        | 1 (2.4%)                     | -                     |
| APR and total ME                               | 0                        | 1 (2.4%)                     | -                     |
| Laparotomy and adhesiolysis                    | 1 (2.5%)                 | 1 (2.4%)                     | 1.00 (0.03-29.81)     |
| <b>Surgical approach</b>                       |                          |                              |                       |
| Midline vertical                               | 25 (62.5%)               | 24 (57.1%)                   | Ref.                  |
| RIF  | 17 (42.5%)               | 16 (38.1%)                   | 1.02 (0.42-2.47)      |
| <b>Duration of surgery (in minutes)</b>        |                          |                              |                       |
| < 60 min                                       | 21 (52.5%)               | 20 (47.6%)                   | 1                     |
| 61-120 min                                     | 11 (27.5%)               | 11 (26.2%)                   | 1.05 (0.37-2.96)      |
| 121-180 min                                    | 8 (20%)                  | 9 (21.4%)                    | 1.18 (0.38-3.67)      |
| >180 min                                       | 0                        | 2 (4.8%)                     | -                     |
| Duration of surgery (mean duration in minutes) | 96.9±38.4                | 99.1±5.8                     | -                     |
| <b>Blood transfusion required</b>              | 34 (85%)                 | 31 (73.8%)                   | 0.212                 |
| <b>Drain</b>                                   |                          |                              |                       |
| Kept   | 14 (35%)                 | 8 (19%)                      | Ref.                  |
| Not kept                                       | 26 (65%)                 | 34 (80.9%)                   | 2.29 (0.84-6.27)      |
| <b>ICU admission required</b>                  | 19 (47.5%)               | 15 (35.7%)                   | 1.38 (0.46-4.16)      |
| <b>Hospital stay</b>                           |                          |                              |                       |
| <5 days  | 17 (42.5%)               | 16 (38%)                     | Ref.                  |
| 06-10 days                                     | 10 (25%)                 | 14 (33.3%)                   | 1.49 (0.52-4.30)      |
| 11-15 days                                     | 7 (17.5%)                | 4 (9.5%)                     | 0.61 (0.15-2.48)      |
| >15 days                                       | 6 (15%)                  | 8 (19%)                      | 1.42 (0.40-4.99)      |
| <b>Type of surgery</b>                         |                          |                              |                       |
| Clean  | 7 (17.5%)                | 4 (9.5%)                     | Ref.                  |
| Clean contaminated                             | 32 (80%)                 | 34 (80.9%)                   | 1.86 (0.50-6.96)      |
| Contaminated                                   | 1 (2.5%)                 | 4 (9.5%)                     | 7.00 (0.57-86.33)     |
| Dirty or infected                              | 0                        | 0                            | -                     |
| Readmission for SSI                            | 0                        | 4 (9.5%)                     | -                     |

**[Table/Fig-2]:** Operative and postoperative variables of patients among groups. Surgical wounds were labelled as clean, clean contaminated & contaminated as per centers for disease control and Prevention/National health care safety network (CDC/NHSN) surveillance definitions [9]; RIF: Right iliac fossa; ME: Mesorectal excision; APR: Abdomino perineal resection; ICU: Intensive care unit.

| Type of SSI     | Care bundle group (n=40) (Case) | Non care bundle group (n=42) (Control) | p-value |
|-----------------|---------------------------------|--|---------|
| Superficial SSI | 4 (10%)                         | 4 (9.5%)                               |         |
| Deep SSI        | 0                               | 4 (9.5%)                               |         |
| Organ space SSI | 0                               | 1 (2.4%)                               |         |
| Total           | 4 (10%)                         | 9 (21.4%)                              | <0.001* |

**[Table/Fig-3]:** Association between type of Surgical Site Infections (SSI) among cases and control. (Pearson's Chi-Square test, \*p value less than 0.05 was considered as statistically significant) Surgical site infections (SSI) were classified as superficial, deep & organ space as per CDC/NHSN surveillance definitions [9]

Depending on the level of contamination, an incidence of 15%-25% is observed in several prospective studies where the rate of SSI are much higher with abdominal surgery compared to other surgeries [11,12].

| Treatment              | Care bundle group (n=40) | Non care bundle group (n=42) | p-value |
|------------------------|--------------------------|------------------------------|---------|
| Antibiotics            | 4 (10%)                  | 9 (21.4%)                    | <0.001* |
| Daily dressing         | 4 (10%)                  | 9 (21.4%)                    | <0.001* |
| Resuturing             | 0                        | 4 (9.5%)                     | 0.67    |
| Exploratory laparotomy | 0                        | 1 (2.4%)                     | 0.34    |

**[Table/Fig-4]:** Association between methods of treatment of SSI among groups. (Fisher's-exact Test; \*- p-value less than 0.05 was considered as statistically significant)

| Organisms isolated                | Care bundle group (n=40) | Non care bundle group (n=42) |
|-----------------------------------|--------------------------|------------------------------|
| <i>Enterococci</i>                | 1 (2.5%)                 | 2 (4.8%)                     |
| <i>Pseudomonas aeruginosa</i>     | 1 (2.5%)                 | 3 (7.1%)                     |
| <i>Staphylococcus aureus</i>      | 1 (2.5%)                 | 2 (4.8%)                     |
| <i>Staphylococcus aureus/MRSA</i> | 1 (2.5%)                 | 1 (2.4%)                     |
| <i>Streptococcus pyogenes</i>     | 0                        | 1 (2.4%)                     |

**[Table/Fig-5]:** Distribution of organisms isolated from wound discharge among cases and controls. MRSA: Methicillin resistant *staphylococcus aureus*

| Duration of surgery | Care bundle group (n=40) | Non care bundle group (n=42) | p-value |
|---------------------|--------------------------|------------------------------|---------|
| <120 min            | 2 (5%)                   | 3 (7.1%)                     | 0.061   |
| >120 min            | 2 (5%)                   | 6 (14.3%)                    | 0.016*  |

**[Table/Fig-6]:** Rate of SSI in relation to duration of surgery among cases and controls. (Pearson's chi-squared test; \*- p-value less than 0.05 was considered as statistically significant)

Postoperative patients who develop SSIs are five times more likely to be readmitted to the hospital, 60% more likely to spend time in the intensive care unit, and twice as likely to die compared with surgical patients without the infections [13]. In patients undergoing colorectal procedures, there is a high risk for postoperative infections due to the risk for contamination during the procedure [14]. Age can be considered as independent predictors of SSI due to multiple factors among geriatric population such as lower immunity, slow healing rate, increased catabolic processes, malnutrition and malabsorption. Special attention to the needs of the geriatric population is warranted with increasing life expectancy [15].

Other co-morbid factors also play important role in SSIs. High serum glucose levels after surgery influence the odds of contracting SSI; therefore, perioperative control of blood sugar should be achieved to prevent SSI [16]. In present care bundle, maintenance of euglycaemia during surgery and in the early postoperative period was an important component although it was not statistically significant. Smoking was associated with SSI in the present study and has previously been shown to correlate with SSI [17]. Cochrane review noted that, interventions of smoking cessation have shown good results on lowering the risk of postoperative infections [18].

Operative time is an independent risk factor for SSI. Parameters such as surgeon experience, preoperative planning, operating room staff experience, surgeon fatigue and access to equipment can impact operating time. Proposed mechanisms by which SSI incidence is increased in laparotomy surgeries are that open incisions are exposed to the environment for longer duration, predisposes incisions to tissue desiccation, tissue concentrations of antibiotics is reduced. Longer operative times often represent more complex surgery procedures, but may also increase room for technical errors and surgical team fatigue [19].

We noted more SSI in surgeries lasting for more than 120 minutes. Duration of surgery was statistically significant with SSI, both in the preintervention and intervention periods [20]. To overcome the decreased concentration of antibiotic that occurs with prolonged operations, re-administration of the antibiotics



is recommended [21]. Cochrane review recommended that antibiotics should be administered both orally with mechanical bowel preparation and intravenously one hour before surgery to reduce SSIs. In our care bundle, we included this component in preoperative preparation [22].

Colorectal surgeries are highly prone to SSI. Wick EC et al., introduced following bundle as preoperative chlorhexidine shower administration; Standardisation of skin preparation; elimination of mechanical bowel preparation in selective cases; in the pre-anaesthesia area warming of patients; enhanced sterile techniques for skin and fascial closure adoption; previously unrecognised lapses to be addressed in antibiotic prophylaxis. After implementation, they observed a 33.3% reduction of SSI's in patients having colorectal surgery [23].

Gorgun E et al, studied SSI prevention by bundle approach in colorectal surgeries. They implemented 14 preoperative, intraoperative and postoperative measures & found that bundle approach is highly effective for reducing SSI [24].

India is one of the leading countries in antibiotic usage in the world, and uncontrolled practices of antibiotic prescription were observed in antibiotic use practices [25]. Later, India formalised its commitment through the 'Chennai Declaration' to reducing SSIs by implementing Antimicrobial Stewardship Programmes [26]. Antimicrobial Stewardship is defined as an 'organisational or healthcare system wide approach to preserve the future effectiveness by promoting and monitoring judicious use of antimicrobials' [27]. Significant reduction of SSIs was noted in care bundle group with comparison of different studies [Table/ Fig-7] [23,24,28,29].

| Studies compared  | Care bundle group | Non care bundle group |
|---|-------------------|-----------------------|
| Wick EC et al., [23]<br>Johns Hopkins University,<br>Baltimore, USA   | 18.2% (n=59/324)  | 27.3% (n=76/278)      |
| Gorgun E et al., [24]<br>Cleveland Clinic, Cleveland,<br>Ohio, USA  | 6.6% (n=83/1264)  | 11.8% (n=116/986)     |
| Bhat AA et al., [28]<br>Sheri Kashmir Institute of<br>Medical Sciences, Srinagar,<br>Jammu and Kashmir, India | 8.7% (n=13/150)   | 18.9% (n=23/122)      |
| Yamamoto T et al., [29]<br>Kobe City Medical Center<br>General Hospital, Kobe, Japan                          | 20% (n=5/25)      | 43% (n=20/47)         |
| Present study<br>Govt Medical College<br>Ernakulam, Kerala, India.  | 10% (n=4/40)      | 21.4% (n=9/42)        |

**[Table/Fig-7]:** Published studies comparing the SSI outcomes after introducing care bundle [23,24,28,29].

Implementation of SSI prevention measures, especially using multimodal strategies that have demonstrated a reduction in colorectal SSIs could have significant implications for clinical acceptance in order to reduce burden of SSIs and improve population health.

### Limitation(s)

This study had a retrospective, single-centre design, therefore possibly introducing some degree of bias. Lack of randomisation, inability to identify which specific elements of the bundle truly contribute to reducing infection, an inherent limitation of all similar studies; and inability to calculate cost savings associated with reduction bundle studies are limiting factors of this study.

### CONCLUSION(S)

Multimodal bundle approach for SSI prevention is an innovative way to reduce SSI burden among patients undergoing lower

gastrointestinal surgeries. Simple preoperative, operative and postoperative interventions can bring down SSI incidence significantly. There is significant reduction in overall, superficial, deep, organ-space SSI rate in laparotomies for lower gastrointestinal surgeries by adoption of evidence based "Care bundle". Prospective, multicenter trials are needed to confirm our results.

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