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A prospective study evaluating the impact of implementing 'bundled interventions' in reducing surgical site infections among patients undergoing surgery for gynaecological Malignancies

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ABSTRACT

Objective: To investigate the incidence of 30-day surgical site infection (SSI) rate before and after the introduction of evidence-based "bundled interventions" (BI) in gynaecological malignancy (GM).To evaluate the efficacy of BI in reducing SSI rate and readmission rate due to SSI.

Methods: This prospective interventional study was carried out at a Single University teaching hospital. BIs were implemented in GM laparotomies from March 2016 to June 2018. Baseline SSI rate was determined retrospectively from January 2011 to December 2015. The interventions included patient education, separate closing tray, dressing removal $\leq$48 h, dismissal with 4% chlorhexidine gluconate and follow up phone call. A 30-day SSI and re-admission rate were assessed.

Results: The study included 840 patients, 624 who underwent laparotomy before (PRE) the implementation of BI and 216 after (POST) the implementation. The most common diagnosis was ovarian cancer (OC). There was significant reduction in: overall ($p < 0.001$) and superficial SSI rates ($p < 0.001$); OC undergoing surgery without bowel resection (BR) ($p < 0.001$); and OC with BR ($p = 0.003$), after implementation of BI. None of the patients had deep organ/space infections or readmissions during the Post-intervention period. The overall compliance for BI was 96.7%. SSI rates significantly decreased in patients aged $\geq$ 60 years, ASA score $\geq$3, operative time $\geq$240 min, clean contaminated and contaminated surgeries, and prolonged hospital stay (all $p < 0.05$).

Conclusion: Implementation of BI was associated with significant reduction of SSI rate in GM. The intervention remained effective in at-risk patients with non-modifiable clinico-pathologic and surgical factors.

Introduction

Surgical site infections (SSIs) were reported as the most common hospital acquired infections (HAIs) by the American College of Surgeons (ACS). SSI account for approximately 20% of documented HAIs; and is most costly of all HAIs. [1] SSIs are associated with significant morbidity in terms of increased length of hospital stay (LOHS) by approximately 10 days, readmission rates, hospitalization costs by approximately $20, 000 per admission, substantial reduction in the quality of life, and increased mortality [1,2]. 2–5% of all in-patient surgeries, including approximately 2% of all hysterectomies are complicated by SSIs [2,3].

Surgery is the cornerstone for the treatment of gynecologic malignancies (GM). The cytoreductive ovarian cancer (OC) surgeries often require radical pelvic and upper abdominal procedures with multi-organ resection. [4] These high complexity surgeries for OC are associated with the substantial risk of SSIs, high perioperative morbidity and poor overall survival. [4] Staging surgery for uterine cancer (UC) via open approach is associated with 15-fold increased risk of SSI compared to minimally invasive approach [5,6].

Recently, there has been a growing interest in implementing new evidence-based "bundled interventions" (BI) in the perioperative time frame for the elimination of SSIs [7–9]. The studies in other sub-specialities have shown considerable reduction in SSI rate with the implementation of BI [9]. However, in the field of gynecology oncology (GO), despite the reported SSI rate of 3–36% for major GM procedures and an approximately 30% hospital

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readmission rate attributable to postoperative SSIs [10–16]; the studies on the use of BI to reduce SSI are scant [17–19].

Given the known elevated rates of SSIs in GM surgeries, as well as the importance of SSI reduction in improving the quality of healthcare, we implemented the evidence based BI in patients undergoing surgery for GM at our institution. The aim of this study was to investigate the SSI rate before and after the BIs implementation, and to evaluate the intervention's efficacy in reducing the overall SSI and readmission rate.

Methods

This prospective quality improvement study was implemented in the department of GO, Amrita Institute of Medical Sciences, Kochi, Kerala, India in March 2016 after taking approval from the institution review board.

Study participants, design and setting

All women who underwent laparotomies for OC, including primary debulking surgery, interval debulking, and surgery for recurrent disease with or without bowel resection (BR); staging laparotomy for UC primary, or recurrent; radical hysterectomy and bilateral pelvic lymph node dissection for cervical cancer (CC) from March 2016 to June 2018 were included. Exclusion criteria were: minimally invasive surgery for GM; operated outside for GM and presented with SSI; and diagnosed to have benign gynaecological condition. Individual patient admissions were used, because patient with recurrent disease may undergo multiple surgeries over the course of their disease.

The prospective data of consecutive patients who underwent laparotomy after the implementation of BIs (POST) was compared with the retrospective cohort of patients before introduction of BIs (PRE).

Cases both in the PRE- and POST-intervention groups were categorized into four sub-cohorts for analysis: 1) OC debulking not requiring BR (OC without BR), 2) OC debulking requiring BR (OC with BR), 3) staging laparotomy for UC, and 4) Radical hysterectomy for CC.

SSI reduction bundled interventions

BIs were implemented in March 2016. Post intervention group was comprised of GM patients operated from March 2016 to June 2018.

The BIs consisted of 14 elements throughout the surgical admission (Table 2). Key components of BIs included patient education, separate closing tray for fascia and skin closure, staff gloves change before fascia closure, gown change if soiled, dressing removal within 24–48 h, dismissal with 4% chlorhexidine-gluconate, and follow up phone call from the institute.

The initiative employed an inter-departmental team composed of surgeons, nurses, pre-surgical testing and operating room personnel, inpatient and outpatient personnel, and staff from wound care and infection control departments. The team was divided into four sections focussing on preoperative, intra-operative, postoperative care; and data collection.

The bundle was formally implemented and audited by the lead gynecologic oncosurgeon. Measures were developed to optimize implementation and patient compliance with the bundle elements. Random audits of the nursing elements were incorporated into routine weekly perioperative nursing care reviews and included providing the patient education pamphlet, hand hygiene, dressing removal, 4% chlorhexidine-gluconate showering after dressing removal, dismissal with 4% chlorhexidine-gluconate, postoperative patient education on wound care and infection symptoms, and follow-up phone call. Antibiotic compliance and cefazolin re-dosing were also audited.

Table 1
Demographic and operative characteristics.

Characteristics	Pre Intervention (n = 624) N (%)	Post Intervention (n = 217) N (%)	P value
Age (in years) Median (Range)	55 (17 - 85)	53 (13–85)	0.079
BMI Mean ± SD	24.9 ± 6.0	25.6 ± 4.3	0.337
ASA	461 (73.9)	177 (81.6)	0.843
1-2	100 (16.0)	40 (18.4)	
≥ 3	63 (10.1)	0	
Unknown			
H/O Diabetes	143 (22.9)	49 (22.6)	0.777
Previous Abdominal Surgeries	337 (54)	114 (52.5)	0.889
0	200 (32.1)	68 (31.3)	
1	57 (9.1)	24 (11.1%)	
2	30 (4.8)	11 (5.1%)	
≥ 3			
Operative time (min)	210 (100 – 800)	200 (75 – 750)	0.052
Estimated blood loss (ml)	290 (100 – 3000)	310 (100 – 3500)	0.181
Procedure	390 (62.5)	158 (72.8)	0.021
OC	36 (5.8)	12 (5.5)	
OC + BR	171 (27.4)	37 (17.1)	
UC	27 (4.3)	10 (4.6)	
CC			
Wound class	111 (17.8)	43 (19.8)	0.677
Clean	403 (64.6)	133 (61.3)	
Clean contaminated	110 (17.6)	41 (18.9)	
Contaminated/Dirty			

PRE-intervention group

PRE-intervention group was comprised of GM patients operated from January 2011 to December 2015. Of note, no significant changes in technology, surgical techniques, surgical team and anaesthesiologist team took place between the PRE- and POST-intervention period.

Interventions unchanged between the groups

Elements in place during both the period included: 4% chlorhexidine-gluconate shower before surgery, prophylactic antibiotic administration; incision area coverage with 2% chlorhexidine-gluconate and 70% isopropyl alcohol solution; redose of cefuroxime within 3–4 h after incision; no mechanical bowel preparation (MBP), and addition of metronidazole in perioperative period in patients requiring bowel resection. Normothermia was maintained in perioperative period, hair removal only when indicated, and continued blood glucose monitoring and control in diabetics.

Outcomes

Aim of our study was the prospective evaluation of efficacy of bundled interventions' in reducing SSI rate in patients undergoing laparotomy for GM. The primary endpoint was the reduction in SSI rate with the BI implementation. Secondary endpoints were: compliance to bundle elements, and readmission rate due to SSI. Overall compliance to bundle elements in POST-intervention group was calculated as the average of all pre-, intra-, post-operative, and post-discharge elements.

The incidence of SSIs was analysed within 30 days of surgery. SSIs were defined according to the Centres for disease control and Prevention's National Healthcare Safety Network category 1B criteria as superficial, deep, and organ or space [20]. Patients with

Table 2
Care bundle protocol compliance in the POST intervention cohort.

Elements	%
Preoperative	
Preventing surgical site infection pamphlet for patient education	96.7
4% chlorhexidine-gluconate shower night before and day of surgery	100
Intraoperative	
Surgical Care Improvement Project compliance with antibiotic administration	100
Coverage of incisional area with 2% chlorhexidine-gluconate and 70% isopropyl alcohol	100
Re-dose of Cefuroxime within 3-4 h after incision	89.8
Sterile closing tray for fascia and skin closure	95.2
Staff glove change before fascia closure; gown change if soiled	95.6
Postoperative	
Practice good hand hygiene	98.6
Hand cleansing agent readily available	99.5
Ensure dressing removal within 24-48 h	98.3
Patient shower with 4% chlorhexidine-gluconate after dressing removal	90.1
Patient education on wound care and infection symptoms	94.8
Post discharge	
Discharge patient with 4-oz bottle of 4% chlorhexidine-gluconate	91.8
Follow up phone call from institute within 24-72 h	93.2
Overall compliance	**96.0**

seroma, discharge or induration at surgical site but microbiology report negative for any infection were not considered to have SSI.

Data collection

30-day SSI data were obtained prospectively through a combination of inpatient assessments, outpatient visits, and routine phone calls conducted by physician assistants.

Statistical Analysis

The Wilcoxon rank sum test was used to compare differences in the central tendencies for continuous variables. Categorical data or differences in proportions were compared with the Pearson Chi-square test. Statistical significance was defined as a p value of < 0.05, significant. All analysis were performed in IBM SPSS for Windows, version 20.0.

Results

Of the 840 identified GM patients between 2011 and 2017, 624 patients underwent laparotomy before (PRE) and 216 after (POST) implementation of BI.

Patients' demographic and surgical characteristics are listed in Table 1. Both the cohorts were similar in demographic and surgical characteristics (P values all > 0.05). The most common diagnosis in both the cohorts was OC but significantly higher number of patients were operated for OC in the POST-intervention era (PRE 68.3% vs POST 79.2%; $p = 0.014$). Significantly lesser number of UC patients underwent laparotomy in POST-intervention period because of the introduction of robotic-assisted surgery in the institute in 2015.

The overall compliance with the various elements of BIs was 96.7% (Table 2). The lowest compliance elements were, redose of cefuroxime within 3–4 h of incision (89.8%), followed in order by shower with 4% chlorhexidine-gluconate after dressing removal (90.1%), and discharge of patient with 4-oz bottle of 4% chlorhexidine-gluconate (91.8%).

The overall SSI rate in the PRE intervention cohort was 16.8% (105/624) compared to 3.7% (8/216; RRR 78%; OR 0.19, 95% CI 0.09–0.39; $p < 0.001$) in the post-intervention cohort. Among OC laparotomies there was a significant drop in SSI rate: OC without BR (PRE 11% (43/390) vs POST 1.9% (3/157); RRR 82.7%; OR 0.15, 95% CI 0.05–0.51; $p < 0.001$); and OC with BR (PRE 58.3% (21/36) vs POST 8.3% (1/12; RRR 85.7%; OR 0.07, 95% CI 0.01–0.56; $p = 0.003$). Among UC, the overall SSI rate declined from 21.6% (37/171) to 10.8% (4/37; RRR 50%; OR 0.44, 95% CI 0.15–1.32; $p = 0.133$), despite the fact that the patients were more likely to have poor performance and functional status, higher number of comorbidities and ASA score, also more likelihood of having sarcoma in the POST intervention cohort. Among CC, overall SSI rate declined from 14.8% (4/27) to 0 (0/10) (Table 3).

The SSI reduction was achieved within the first year of BI and was maintained in the second and third year. In the post intervention cohort all patients had superficial SSI [PRE 12% (75/624) vs POST 3.7% (8/216); $p < 0.001$]; none of the patients had deep [PRE 3.5% (22/624) vs POST 0.0% (0/216)]; and organ/space [PRE 1.3% (8/624) vs POST 0.0% (0/216)] SSI. None of the patients in POST intervention cohort were readmitted with SSI [PRE 1.6% (10/624) vs POST 0.0% (0/216)] (Table 4).

Subset analysis of pre and post intervention cohort SSI rates was done based on various clinical and procedure based variables (Table 5). At-risk demographic and surgical variables associated with significant decrease in SSI rate in post intervention cohort were: age $\geq$ 60 years; ASA score ≥ 3; operative time ≥ 240 min; clean contaminated and contaminated surgeries; and patients with prolonged length of hospital stay more than the median LOHS. There was decrease in SSI rate in patients with recurrent

Table 3
Rates of Surgical Site Infections in PRE- and POST- intervention cohorts.

Type of Surgery	PRE-intervention	POST-intervention	P[a]	RRR (%)	OR (95% CI)
Overall	16.8 (105/624)	3.7 (8/216)	< 0.001	78.0	0.19 (0.09 – 0.39)
OC	11.0 (43/390)	1.9 (3/157)	<0.001	82.7	0.15 (0.05 – 0.51)
OC + BR	58.3 (21/36)	8.3 (1/12)	0.003	85.7	0.07 (0.01 – 0.56)
UC	21.6 (37/171)	10.8 (4/37)	0.133	50	0.44 (0.15 – 1.32)
CC	14.8 (4/27)	0 (0/10)	-[b]	-[b]	-[b]

[a] Fischer exact test.
[b] Did not estimate p value and OR given the lack of event in POST-intervention period.

Table 4
Types of SSI and Re-admission rate due to SSI in PRE- and POST- intervention cohorts.

	PRE-intervention	POST-intervention	P
Superficial	12.0 (75/624)	3.7 (8/216)	< 0.001
OC	9.0 (35/390)	1.9 (3/157)	
OC + BR	25.0 (9/36)	8.3 (1/12)	
UC	15.8 (27/171)	10.8 (4/37)	
CC	14.8 (4/27)	0 (0/10)	
Deep	3.5 (22/624)	0 (0/216)	–
OC	1.3 (5/390)	0 (0/157)	
OC + BR	25.0 (9/36)	0 (0/12)	
UC	4.7 (8/171)	0 (0/37)	
CC	0 (0/27)	0 (0/10)	
Organ Space	1.3 (8/624)	0 (0/216)	–
OC	0.8 (3/390)	0 (0/157)	
OC + BR	8.3 (3/36)	0 (0/12)	
UC	1.2 (2/171)	0 (0/37)	
CC	0 (0/27)	0 (0/10)	
Readmission	1.6 (10/624)	0 (0/216)	–
OC	1.3 (5/390)	0 (0/157)	
OC + BR	2.8 (1/36)	0 (0/12)	
UC	2.3 (4/171)	0 (0/37)	
CC	0 (0/27)	0 (0/10	

Table 5

Characteristics	Pre intervention	Post intervention	P value
Age ≥ 60years SSI rate	47/223 (21.1)	3/66 (4.5)	0.002
ASA score 3 or 4 SSI rate	25/108 (23.2)	4/44 (9.1)	0.045
Operative time ≥ 240 min SSI rate	59/294 (20.1)	5/82 (6.1)	0.003
Clean contaminated surgeries SSI rate	65/403 (16.1)	5/133 (3.8)	< 0.001
Contaminated surgeries SSI rate	27/110 (24.5)	2/40 (5.0)	0.007
LOHS > 6 days[a] SSI	62/261 (23.8)	3/37 (8.1)	0.03

[a] 6 days is the Median LOHS of PRE-intervention period and same was taken for POST-intervention period also so as to obviate the bias.

surgery [PRE 20.6% (13/63) vs POST 7.1% (1/14); p = 0.236] but could not reach statistical significance.

Discussion

In the current prospective, single-institution study, a significant reduction in 30-day SSI rate, readmission rate, and SSI rate in at-risk GM surgeries with the implementation of Bis was observed.To our knowledge, this is the first prospectively studied evaluation of evidence based surgical site infection reduction “BIs” in India.

In 2006 Surgical Care Improvement Project (SCIP) was initiated with the aim to reduce the rates of surgical complications such as SSI [21]. The SCIP initiative were focused on: standardizing timing, type and duration of antibiotics; glucose control; hair removal; and normothermia [22]. Despite the high compliance to the SCIP guidelines, these interventions individually have not proven to lower SSI rates, and suggested the need for additional interventions [23,24]. Consistent with the available evidences in literature, we also found that despite strict adherence to the SCIP guidelines, baseline SSI rate in current study was as high as 16.8% in the PRE-intervention cohort.

Based on the published literature, the SSI rates for major GM procedures ranged from 3 to 36%. [11–15,17–19]. In concordance with the various published series, the baseline SSI rate in current study is 16.8%. 11% SSI rate in OC, 21.6% in UC, and 14.8% in CC laparotomies. SSI rate among OC with BR laparotomies was 58.3% which was unexpectedly greater than that reported in literature.

The efficacy of BIs in gynaecological malignancy has been evaluated scarcely [17–19].First study was published by Jhonson et al. [17]. Interventions included was: preoperative chlorhexidine wash, separate fascial closure tray, gloves change, and postoperative daily showering with chlorhexidine solution. The authors reported a significant reduction in the SSI rate from 6% to 1.1% with a relative risk reduction (RRR) of 82.4%. SSI rate reduction was greatest in OC without BR cohort of 2.4% with a RRR of 77.6%. Using the similar reduction bundle, we demonstrated significant reduction in overall SSI rate ($p < 0.001$) with a RRR of 78%. We also found significant reduction in the superficial SSI rate ($p < 0.001$). Compared to the previous study the greatest reduction was observed in OC with BR sub-cohort (RRR 85.7%).

Lippitt et al. demonstrated significant reduction in SSI rate from 20% to 3% in OC cytoreductive surgeries with the implementation of five-point SSI prevention bundle [18]. Intervention included preoperative chlorhexidine wash, MBPwith oral antibiotics, separate fascia closure tray, and gown and gloves change. SSI rate reduced from 33% to 7% in OC with BR laparotomies Our results compared favourably to the results of previous study, despite the non-inclusion of MBP with oral antibiotics element in our BI. The overall 30-day SSI rate in OC patients decreased from 15% to 2.4%, and in OC with BR laparotomies decreased from 58.3% to 8.3%. None of the patients in the post-intervention cohort were re-admitted with SSI.

In current study, despite the non-inclusion of MBP a significant reduction in SSI rate in ovarian cancer surgeries requiring bowel resection was demonstrated. Our findings are akin to the study by Schiavone et al. The authors investigated the efficacy of SSI reduction bundle in GM patients undergoing colon surgery [19]. In their study the novel aspects of care included preoperative chlorhexidine wash, oral antibiotics ± MBP, and separate closing trays with gloves change. Notably the authors reported a significant reduction in the overall 30-day SSI and wound dehiscence rate ($p < 0.001$).

Various studies have identified at-risk factors associated with increased risk of SSI [25,26]. We did the subset analysis to identify the efficacy of BIs in reducing SSI rate among at-risk demographic and surgical factors. There were significant decrease in SSI rate in patients' ≥ 60 years of age, higher ASA score, longer operating time (≥ 240 min), clean contaminated and contaminated surgeries, and prolonged LOHS. The present study separately looked into the decrease in SSI rate in patients with recurrent surgery, and found a decrease of 7.1% from 20.6%, however the statistical significance could not be reached, may be because of less number of patients undergoing recurrent surgery. Schiavone et al. reported a significant decrease in SSI rates in high risk groups as age ≥ 65 years, operating time ≥ 360 min, blood loss ≥ 500 ml, and patients having stoma or underwent hysterectomy [19].

Waits et al. described a strengthened the bundling concept by illustrating an inverse association between number of bundle elements implemented and risk-standardized SSI rate [9]. Thompson et al. mentioned that the committed leadership, high compliance with the various elements of SSI bundle, achievement of high level of staff engagement, and centralization of critical surgical activities are the keys to the success of an SSI reduction bundle program [27]. To the best of our knowledge current study is the first in literature of GMwhere the compliance rate with the specific elements of BIs and overall compliance rate of 96% are reported.

Strengths of this study include the prospective study design, inclusion of a high-volume patient population undergoing surgery for GM at a comprehensive-cancer centre, utilization of an evidence based protocol that was audited regularly, independent

data collection by a trained infection prevention specialist, and detection and diagnosis of SSI based on microbiology henceforth avoidance of detection/reporting bias.

Our current trial is not without limitations. Single institution, PRE-intervention cohort being retrospective in nature; lack of randomization; inability to identify which specific elements of the bundle truly contribute to infection reduction, an inherent limitation of all reduction bundle studies; and inability to calculate associated cost savings are the limiting factors of this study.

In summary, adoption of evidence based "bundled interventions" was associated with significant reduction in overall, superficial, deep, organ/space SSI rate and 30-day readmission rates in laparotomies for GM. The intervention remained effective in at-risk patients with non-modifiable clinico-pathologic and surgical factors. The prospective data add to a robust body of work [17–19]. suggesting that adoption of BIs is associated with significant improvement in SSI rates in patients undergoing surgery for GM.

Conflict of intrest

Authors declare that there are no conflicts of intrest.

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