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Implementation of a surgical site infection prevention bundle in gynecologic oncology patients: An enhanced recovery after surgery initiative

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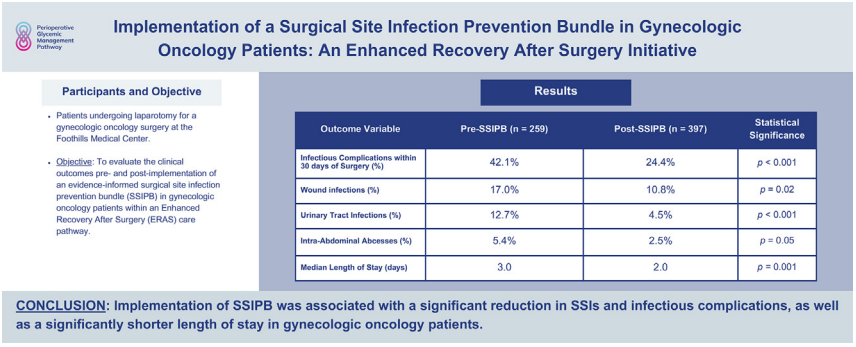
HIGHLIGHTS

- A Surgical Site Infection Prevention Bundle (SSIBP) requires coordination between healthcare providers.
- Evaluating the implementation of a SSIBP in gynecologic oncology patients is challenging.
- SSIPB Implementation is associated with improved surgical outcomes: shorter length of stay and fewer infections.

GRAPHICAL ABSTRACT



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ABSTRACT

Objective. To evaluate the clinical outcomes pre- and post-implementation of an evidence-informed surgical site infection prevention bundle (SSIPB) in gynecologic oncology patients within an Enhanced Recovery After Surgery (ERAS) care pathway.

Methods. Patients undergoing laparotomy for a gynecologic oncology surgery between January–June 2017 (pre-SSIPB) and between January 2018–December 2020 (post-SSIPB) were compared using *t*-tests and chi-square. Patient characteristics, surgical factors, and ERAS process measures and outcomes were abstracted from the ERAS® Interactive Audit System (EIAS). The primary outcomes were incidence of surgical site infections (SSI) during post-operative hospital admission and at 30-days post-surgery. Secondary outcomes included total postoperative infections, length of stay, and any surgical complications. Multivariate models were used to adjust for potential confounding factors.

Results. Patient and surgical characteristics were similar in the pre- and post-implementation periods. Evaluation of implementation suggested that preoperative and intraoperative components of the intervention were most consistently used. Infectious complications within 30 days of surgery decreased from 42.1% to 24.4% after implementation of the SSIPB ($p < 0.001$), including reductions in wound infections (17.0% to 10.8%, $p = 0.02$), urinary tract infections (UTI) (12.7% to 4.5%, $p < 0.001$), and intra-abdominal abscesses (5.4% to 2.5%,

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$p = 0.05$). These reductions were associated with a decrease in median length of stay from 3 to 2 days ($p = 0.001$). In multivariate analysis, these SSI reductions remained statistically significant after adjustment for potential confounders.

Conclusion. Implementation of SSIPB was associated with a reduction in SSIs and infectious complications, as well as a shorter length of stay in gynecologic oncology patients.

1. Introduction

Surgical site infections (SSIs) are associated with worse outcomes for gynecologic oncology patients, including longer hospital stays [1], greater readmission rates [2], and higher mortality [3,4]. In addition, each SSI costs the healthcare system an estimated $5500 [5] to $10,500 USD [6]. Gynecologic oncology patients have a high prevalence of individual and surgical risk factors for SSI, including higher body mass index (BMI) [7,8], insulin resistance or diabetes [5,8], urinary catheter insertion and surgical approach via laparotomy [5]. The incidence of SSI after gynecologic oncology surgery ranges from 3% [9] to 16% [7,10] and as high as 53% [11], depending on the population and outcome ascertainment method.

Fortunately, many of the risk factors for SSIs are modifiable. The ERAS 2019 guidelines have recommended the implementation of SSIPB for gynecologic oncology patients undergoing laparotomy [12]. However, implementation of these bundled interventions have been variably associated with reductions in SSIs [10,13–17]. The purpose of this quality improvement study was to evaluate the impact of a standardized, evidence-informed Surgical Site Infection Prevention Bundle (SSIPB) in gynecologic oncology patients at our centre.

2. Methods

2.1. Study design

This pre- and post-intervention study evaluated the impact of a multi-stage pathway (the SSIPB) on clinical outcomes in patients undergoing surgery for gynecologic malignancy. Ethics approval was obtained from the Conjoint Health Research Ethics Board of the University of Calgary, Alberta, Canada (HREBA.CC-16-0201). The study followed the Standards for Quality Improvement Reporting Excellence (SQUIRE-2) reporting guideline [18].

2.2. Setting

The gynecologic oncology service at the Foothills Medical Centre in Calgary, Alberta, Canada, serves all patients with a gynecologic malignancy in Southern Alberta. The catchment area for this referral center includes approximated 2.5 million people. All gynecologic oncology patients are managed according to the Enhanced Recovery After Surgery (ERAS) pathway for gynecologic oncology [19–21]. Baseline ERAS® audits in our center suggested that 42% of patients who underwent a gynecologic oncology procedure had a postoperative infection, of which 21% were SSIs.

2.3. Population

All adult patients undergoing elective surgery for a confirmed or suspected cancer and admitted to hospital for >24-h after a laparotomy for a gynecologic oncology procedure with a planned OR time between January–June 2017 (pre-SSIPB) and between January 2020–December 2020 (post-SSIPB) were included. Staging procedures encompassed one or more of the following: hysterectomy or radical hysterectomy, bilateral salpingo-oophorectomy, pelvic lymphadenectomy, para-aortic lymphadenectomy, appendectomy, omentectomy. In contrast, debulking procedures involved staging procedures plus one or more of the following: diaphragm stripping, large bowel resection, liver resection, small bowel resection, splenectomy, urologic diversion, removal of retroperitoneal mass, partial cystectomy, partial gastrectomy. Procedures for endometrial cancer, ovarian cancer (organ confined and metastatic disease) and cervical cancer were included. Patients who underwent a laparoscopic procedure, emergency procedures, pregnant patients, or those younger than 18 years were excluded.

2.4. Intervention

The Surgical Site Infection Prevention Bundle (SSIPB) is a multidisciplinary pathway based on ERAS [12], CDC [22,23] and WHO [24] checklists for reducing SSIs. These checklists were combined and adapted for our setting based on the level of evidence of effectiveness of each recommendation and feasibility of their implementation at our center by a team of gynecologic oncology surgeons. The SSIPB contains preoperative, intraoperative, and postoperative items that aim to reduce infections among surgical patients (eTable 1). An Infection Prevention and Control practitioner provided guidance on implementation and sustainable monitoring of implementation.

The SSIPB included a single page checklist of 20 items placed at the front of the patient chart as part of the surgical booking process. The preoperative items of the checklist were addressed with the patient during the usual preoperative patient teaching by nurse educators in the outpatient clinic. The preoperative holding portion of the checklist was completed by nurses in the day surgery unit, the intraoperative portion was performed by the circulating nurse and operating surgeon, and the postoperative portion was completed by the unit staff nurse as part of the standards of care for postoperative patients. Checklist completion was monitored at 6-month intervals and issues or changes communicated with the appropriate teams. After 1 year, the checklist was streamlined based on feedback from end users. The specific user groups responsible for completion of each section were added. In addition to the SSIPB changes, after the pre-implementation cohort there were some additional institutional changes. During the summer of 2019, a procedural enhancement was implemented in the day surgery area, involving the introduction of warming gowns. This initiative aimed to pre-warm patients before their arrival at the operating room, the warming gowns were used on the upper body of all patients throughout the surgery. At the same time, routine application of an adhesive anchoring device for urinary catheters was placed on all patients at the end of each surgical procedure.

The pre-intervention period was January 1, 2017, to June 30, 2017. The SSIPB was implemented on January 1, 2018, and the compliance to the checklist was iteratively improved with audit and feedback to the stakeholder from January 2018 to December of 2019. The data collection for the post-implementation period started on January 1, 2020 and continued until the December 31, 2020. Prior to implementation, site sponsorship was obtained. The process of site sponsorship involves leadership engagement to ensure support and endorsement for the SSIPB. Leadership involvement is critical to help facilitate the implementation process. Process mapping was used to identify which care elements would represent a change in practice such as chlorhexidine

showering by patients, use of closing trays in the operating room, standardized wound care, and patient follow-up for wound concerns. Strategies to support these practice changes were addressed pre-implementation with stakeholders and end users.

Nursing groups were educated about implementation and administration of the SSIBP during their usual education rounds and surgeons were educated during their weekly grand rounds and during the academic half-day for the residents. This implementation education focused on role clarification of who was responsible for which tasks and incorporating each checklist item into the workflows or systems of the appropriate setting. For example, information about preoperative chlorhexidine washes and smoking cessation were incorporated into the patient education bundles given to all patients booked for gynecologic oncology surgery. In the operating room, the nurses set aside a bundle of instruments for the abdominal closure, these remain sterile and unused for the entire surgery. Prior to commencing closure of the abdomen, all instruments used to date are cleared from the surgical field and the surgical team changes their gloves. Only sterile instruments in the bundle are used for the abdominal closure. Ward nurses also updated their dressing protocols to include saline irrigation and specialized wound care items.

2.5. Data & measures

Patient characteristics, surgical factors, and ERAS process measures and outcomes were abstracted from the ERAS® Interactive Audit System (EIAS) as the data repository used by ERAS Alberta, under the Surgery Strategic Clinical Network™ of Alberta Health Services. Patient data at the time was housed in a hybrid system within an electronic health record EHR (Sunrise Clinical Manager; Allscripts, Richmond, British Columbia, Canada) and Netcare (Alberta Health Services) along with some physical chart records. Personal healthcare numbers were used to create individual-level linkages across all databases used in this study. Procedure codes and surgical duration, based on the Canadian Classification of Health Interventions, were obtained from Picis Patient Management Software (Wakefield, Mass). Administrative data captured in our setting is near complete. Data that was not available in the EHR was collected by chart audit for all eligible patients during the study period.

Patient factors included the American Society of Anesthesiologist Classification (ASA), tobacco use, diabetes status and hemoglobin A1c (for patients with diabetes), and body mass index (BMI, kg/m^2). Surgical factors were surgical incision type (midline or low transverse), surgical wound class (as estimated by the attending surgeon according to the WHO classification [25], from clean to dirty), surgery duration, and whether a bowel anastomosis occurred. A surgical complexity score was calculated for each procedure using the tool developed by Aletti et al. 2007 [26]. According to this scoring system, the following procedures were assigned a score of 1: total hysterectomy with bilateral salpingo-oophorectomy (TAH-BSO), omentectomy, pelvic lymphadenectomy, paraaortic lymphadenectomy, pelvic peritoneum stripping, and abdominal peritoneum stripping. Similarly, procedures such as large bowel resection, Diaphragm stripping/resection, Splenectomy, and Liver resections were allotted a score of 2. Lastly, rectosigmoidectomy with transverse-transverse anastomosis received a score of 3. The cumulative scores were subsequently stratified into three categories: Low complexity, defined as a score of 3 or fewer; Intermediate complexity, encompassing scores between 4 and 7; and High complexity, denoting scores of 8 or more (Table 2). ERAS process measures included preoperative antibiotic administration, use of an intraoperative warming device, and time to urinary catheter removal.

Clinical outcomes that occurred during the surgical admissions and within 30 days of surgery were retrieved for all study patients as defined and coded as per EIAS and ERAS Alberta data definitions. Chart review and coding was performed primarily by a trained single team member with Gynecologic Oncology experience. The highest overall classification of all complications based on Clavien-Dindo [27] (which ranges from Grade I to Grade V, where Grade V complications lead to death of the patient) was assigned. Infectious complications were captured under the category of any infectious complication (including all subcategories) and further subdivided into: wound infection, urinary tract infection (UTI), intra or retroperitoneal abscess, sepsis, septic shock, and other infectious complications for those infections not meeting criteria in the other categories (eTable 2). ERASAb coding adheres to the EIAS standards and the ERASAb data dictionary, serving as the framework for coding Surgical Site Infections (SSI). Per the EIAS definition, the diagnosis of a wound infection requires: Skin closure opened spontaneously, bedside or by surgical debridement AND a positive swab cultured from the skin incision OR presence of frank pus. This does not include infections that are part of an intraperitoneal or retroperitoneal abscess. The EIAS definition for abscess is an intraperitoneal or retroperitoneal abscess that is diagnosed radiographically or at the time of reoperation. ERASAb incorporates clinical judgment in the coding process. Specifically, instances where antibiotics were prescribed, and a physician documented the presence of "wound infection," were also coded accordingly in the system. Total surgical site infection is a composite score of the number of patients who experienced a post-op wound infection or intra-peritoneal abscess. Nights spent in an intensive care unit (ICU), 30-day readmissions and length of stay (number of nights) were also extracted from EIAS.

2.6. Statistical analysis

Categorical variables were summarized using number (percentage). Mean (standard deviation [SD]) and median (interquartile range [IQR]) were used for continuous variables. To compare the difference between pre-SSIPB and post-SSIPB patient and surgical characteristics, *t*-tests and $\chi 2$ tests were used for continuous and categorical variables, respectively.

Multivariate analysis was conducted using patient and surgical factors (age, BMI, preoperative nutrition status, diabetes, smoking status, intraoperative blood loss, length of operation, ASA, heated IV fluid, and core body temperature) as predictors for the primary and secondary outcomes. Logistic regression was used for dichotomous outcomes (reported as odds ratios [OR]) and negative binomial regression was used for continuous outcomes (reported as absolute changes). Backward stepwise variable elimination was used to create parsimonious models. Predictors were only included in the final model if the probability value for their association was 2-sided $p < 0.05$. All analyses were completed using Stata version 13 (College Station, TX, US) [28].

3. Results

3.1. Patient and surgery characteristics

There were 656 eligible patients who underwent a gynecologic oncology procedure during the study period: 259 in the pre-SSIPB (39.5%) cohort and 397 in the post- SSIPB (60.5%) cohort (Table 1). There was no difference in the type of oncology procedure between the pre- and post-intervention groups: 76.8% staging and 23.2% debulking compared to 79.1% staging and 20.9% debulking procedures respectively ($p = 0.49$). The staging procedures include organ confined endometrial, cervical, and ovarian cancer, the debulking procedures are for metastatic ovarian cancer (Table 2). Post-intervention patients were older and had higher ASA class than pre-intervention patients (median age 60 years [IQR 50–69] compared to 57 years [IQR 49–66], $p = 0.04$, and 38.1% [151/397] versus 28.1% [72/259] were assessed as ASA 3 or 4, $p = 0.05$). Surgeries in the post-intervention period had more

Table 1
Patient and surgical characteristics in the pre- and post-implementation period for the Surgical Site Infection Prevention Bundle.

Characteristic	All patients (n, %)	Pre-intervention (n, %)	Post-intervention (n, %)	p-value
Time period	January 1, 2017, to December 31st, 2020	January 1, 2017, to June 30, 2017	January 1, 2018, to December 31st, 2020	
Number (%)	656	259 (39.5)	397 (60.5)	
Patient Characteristics				
Age (years, median, IQR)	59.0 (50.0–67.0)	57.0 (49.0–66.0)	60.0 (50.0–69.0)	0.04
BMI (m/kg^2, median, IQR)	29.0 (24.0–35.7)	29.7 (24.2–36.5)	28.5 (23.8–35.3)	0.31
Used tobacco	88 (13.6)	36 (14.0)	52 (13.3)	0.93
Had diabetes	97 (14.8)	30 (11.6)	67 (16.9)	0.16
Hemoglobin A1c (%, median, IQR)	7.1 (6.6–8.1)	7.9 (6.8–9.3)	7.1 (6.6–8.0)	0.34
ASA Class				
1	57 (8.7)	26 (10.2)	31 (7.8)	0.05
2	373 (57.1)	158 (61.7)	215 (54.2)	
3	217 (33.2)	71 (27.7)	146 (36.8)	
4	6 (0.9)	1 (0.4)	5 (1.3)	
Pre-operative chemotherapy	58 (8.8)	25 (9.7)	33 (8.3)	0.56
Pre-operative radiotherapy	11 (1.7)	6 (2.3)	5 (1.3)	0.30
Surgical Characteristics				
Duration (minutes, median, IQR)	110 (86–141)	102 (81–130)	115 (90–142)	0.69
Antibiotic prophylaxis pre-incision	645 (98.5)	252 (97.7)	393 (99.0)	0.18
Type of incision				
Midline	464 (71.5)	195 (75.6)	269 (68.8)	<0.01
Low transverse	185 (28.5)	63 (24.4)	122 (31.2)	
Bowel anastomosis	54 (8.23)	27 (10.4)	27 (6.8)	0.10
Intraoperative blood loss (mL, median, IQR)	250 (200–400)	225 (150–400)	250 (200–400)	0.69
Peritoneal soiling				
Clean contaminated	581 (88.6)	249 (96.1)	332 (83.6)	<0.001
Local pus/Contaminated	70 (10.7)	7 (2.7)	63 (15.9)	
Feces, pus, or blood/infection	5 (0.8)	3 (1.2)	2 (0.5)	

BMI = body mass index; IQR = interquartile range; ASA = American Society of Anesthesiologists.

contaminated peritoneal soiling than the pre-intervention period (16.4% [65/397] compared with 3.9% 10/259], $p < 0.001$) and more often used a low transverse incision (31.2% [122/397] versus 24.4% [63/259], $p < 0.01$). After implementation, the median core body temperature increased from 36.4 °C to 36.8 °C ($p < 0.001$; Table 3). There was no difference in the number of patients who quit smoking. Compliance to the ERAS® pathway was calculated to be near 68% for each of the years between 2017 and 2020.

3.2. Clinical outcomes

After implementation, total infectious complications were reduced during the surgical admission from 10.0% to 4.0% ($p = 0.002$) Table 3. The incidence of total SSIs during the surgical admission decreased from 3.9% to 2.0% ($p = 0.16$). The decrease in UTIs was statistically significant from 4.6% to 1.8% ($p = 0.03$). The proportion of patients who had one or more surgical complication during their surgical admission

Table 2
Surgical procedures in the pre- and post-implementation period for the Surgical Site Infection Prevention Bundle.

Procedures	All patients (n, %)	Pre-intervention (n, %)	Post-intervention (n, %)	p-value
Number	656	259	397	
Type of Oncologic procedure				0.49
Staging	513 (78.2)	199 (76.8)	314 (79.1)	
Debulking	143 (21.8)	60 (23.2)	83 (20.9)	
Hysterectomy	499 (76.1)	196 (75.7)	303 (76.4)	0.85
Radical Hysterectomy	37 (5.6)	15 (5.8)	22 (5.5)	0.89
Bilateral Salpingo-oophorectomy (BSO)	605 (92.2)	240 (92.7)	365 (91.9)	0.65
Omentectomy	185 (28.2)	78 (30.1)	107 (27.0)	0.38
Bilateral pelvic lymphadenectomy	349 (53.2)	167 (64.5)	182 (45.8)	<0.001
Paraaortic lymphadenectomy	136 (20.7)	67 (25.9)	69 (17.4)	0.01
Large Bowel Resection	43 (6.6)	24 (9.3)	19 (4.8)	0.02
Diaphragm Stripping	6 (0.9)	2 (0.8)	4 (1.0)	0.76
Splenectomy	3 (0.5)	3 (1.2)	0 (0.0)	0.03
Liver Resection	1 (0.2)	0 (0.0)	1 (0.3)	0.42
Small Bowel Resection	23 (3.5)	13 (5.0)	10 (2.5)	0.09
Partial Cystectomy	6 (0.9)	0 (0.0)	6 (1.5)	0.05
Appendectomy	173 (26.4)	83 (32.1)	90 (22.7)	0.01
Retroperitoneal Tumor Resection	55 (8.4)	0 (0.0)	55 (13.6)	< 0.001
Secondary debulking surgery	8 (1.2)	0 (0.0)	8 (2.0)	0.02
Surgical Complexity Score				0.008
Low	519 (79.1)	192 (74.1)	327 (82.4)	
Intermediate	130 (19.8)	61 (23.6)	69 (17.4)	
High	7 (1.07)	6 (2.3)	1 (0.3)	

Table 3
Implementation and clinical outcomes pre- and post-implementation of the Surgical Site Infection Prevention Bundle.

Outcome	All patients (n, %)	Pre-intervention (n, %)	Post-intervention (n, %)	p-value
Number (%)	656	259 (39.5)	397 (60.5)	
Implementation Outcomes				
Stopped smoking because of surgery	6 (0.9)	2 (0.8)	4 (1.0)	0.93
Core body temperature value (°C, median, IQR)	36.7 (36.3–37.0)	36.4 (36.1–36.8)	36.8 (36.5–37.0)	P < 0.001
Clinical Outcomes (Hospital stay)				
Surgical complications	114 (17.4)	53 (20.5)	61(15.4)	0.09
Urinary tract injury	4 (0.6)	3 (1.2)	1 (0.3)	0.15
Mechanical bowel obstruction	4 (0.6)	3 (1.2)	1 (0.3)	0.15
Post-op paralytic ileus	25 (3.8)	11 (4.3)	14 (3.5)	0.64
Intra-op haemorrhage	21 (3.2)	12 (4.6)	9 (2.3)	0.09
Post-op haemorrhage	4 (0.6)	1 (0.4)	3 (0.8)	0.55
Other surgical complications	88 (13.4)	40 (15.4)	48 (12.1)	0.22
Any infectious complication	42 (6.4)	26 (10.0)	16 (4.0)	0.002
Urinary tract infection	19 (2.9)	12 (4.6)	7 (1.8)	0.03
Total surgical site infections*	18 (2.7)	10 (3.9)	8 (2.0)	0.16
Wound infection	11 (1.7)	5 (1.9)	6 (1.5)	0.68
Abscess	9 (1.4)	6 (2.3)	3 (0.8)	0.09
Clinical Outcomes (30-days)				
Surgical complications	134 (20.4)	58 (22.4)	76 (19.1)	0.31
Urinary tract injury	4 (0.6)	3 (1.2)	1 (0.3)	0.15
Mechanical bowel obstruction	9 (1.4)	6 (2.3)	3 (0.8)	0.09
Post-op paralytic ileus	27 (4.12)	11 (4.3)	16 (4.0)	0.89
Other surgical complications	102 (15.6)	42 (16.2)	60 (15.1)	0.70
Any infectious complication	206 (31.4)	109 (42.1)	97 (24.4)	<0.001
Urinary tract infection	51 (7.8)	33 (12.7)	18 (4.5)	<0.001
Total surgical site infections*	103 (15.7)	54 (20.9)	49 (12.3)	0.003
Wound infection	87 (13.3)	44 (17.0)	43 (10.8)	0.02
Abscess	24 (3.7)	14 (5.4)	10 (2.5)	0.05
Clinical Outcomes (overall)				
Any complication	228 (34.8)	103 (39.8)	125 (31.5)	
Clavien-Dindo grading of complications				
Grade I	79 (34.7)	32 (31.1)	47 (37.6)	0.18
Grade II	131 (57.5)	60 (58.3)	71 (56.8)	
Grade IIIa	5 (2.2)	5 (4.9)	0	
Grade IIIb	7 (3.1)	4 (3.9)	3 (2.4)	
Grade IV	3 (1.2)	1 (1.0)	2 (1.6)	
Grade V	3 (1.2)	1 (1.0)	2 (1.6)	
Need for ICU (days per patient, mean, SD)	0.20 (2.22)	0.06 (0.50)	0.31 (2.97)	0.35
Readmitted at 30-days	32 (4.9)	17 (6.6)	15 (3.8)	0.10
Length of hospital stay (days, median, IQR)	3 (2–4)	3 (2–4)	2 (2–3)	0.001

IQR = interquartile range; SD = standard deviations; ICU = intensive care unit.
* Total surgical site infection is a composite score of the number of patients who experienced a post-op wound infection or intra-peritoneal abscess.

decreased by 5.1% (20.5% to 15.4% $p = 0.09$). There was no change in the clinical severity of these complications after implementation.

At 30-days postoperative, total SSI rate decreased from 20.9% to 12.3% ($p = 0.003$). The reduction in SSIs occurred for both deep space abscesses: 5.4% to 2.5% ($p = 0.05$) and superficial or deep wound infections: 17.0% to 10.8% ($p = 0.02$). There was also a reduced rate of UTIs from 12.7% to 4.5% ($p < 0.001$). Median length of stay in hospital also decreased after implementation by 1-day (3 days [IQR 2–4 days] to 2 days [IQR 2–3 days]; $p < 0.001$); There was no reduction in the need for ICU or 30-day readmissions.

Table 4
Univariate and multivariate regression of association of implementation of the SSIPB with primary and secondary study outcomes.

Outcome Measures	Univariate Model			Multivariate Models**		
	OR	95% CI	p-value	OR	95% CI	p-value
Total SSI during hospital stay*	0.51	0.20 to1.32	0.16	0.64†	0.23 to 1.76	0.39
Total SSI at 30-days*	0.53	0.35 to 0.82	0.004	0.54‡	0.35 to 0.84	0.006
Readmissions within 30-days	0.55	0.27 to 1.12	0.10	0.55§	0.26 to1.16	0.12
	Effect Size	95% CI	p-value	Effect Size	95% CI	p-value
Nights in ICU (n)	0.25	−0.33 to 0.84	0.39	0.21***	−0.37 to 0.79	0.48
Length of stay (days)	−0.28	−0.38 to −0.17	<0.001	−0.22****	−0.32 to −0.12	<0.001

SSI = surgical site infection; OR = odds ratio; CI = confidence interval; ICU = intensive care unit.
* Total surgical site infection is a composite score of the number of patients who experienced a post-op wound infection or intra-peritoneal abscess.
** Predictors were only included in the multivariate models if the probability value for their association with the outcome was a 2-sided *p*-value <0.05.
† Adjusted for length of operation.
‡ Adjusted for body mass index.
§ Adjusted for intra-operative blood loss.
*** Adjusted for diabetes.
**** Adjusted for age, intra-operative blood loss, ASA physical status class, surgical complexity group.

In univariate analysis, the SSIBP was associated with a reduction in total SSIs within 30-days of surgery (OR 0.53; 95% CI 0.35–0.82; $p = 0.004$). In multivariate analysis, only BMI was associated with increased risk of total SSI at 30-days postoperative ($p < 0.001$). After adjusting for patient BMI, the odds of developing total SSI at 30-days after surgery decreased significantly after implementation of the SSIBP (OR 0.54; 95% CI 0.35 to 0.84; $p = 0.006$; Table 4). There was no change in incidence of SSI during the surgical admission, 30-day readmissions, or nights spent in ICU (Table 4). In univariate analysis, SSIBP was also associated with shorter length of stay (−0.28 days; 95% CI -0.38 to −0.17 days; $P < 0.001$). This effect persisted in the multivariate analysis after adjustment for age, intraoperative blood loss, ASA class and surgical complexity score (−0.22 days; 95% CI -0.32 to −0.12 days; $p < 0.001$).

3.3. Implementation

Implementation followed the Quality Implementation Framework (QIF) [29,30]. The QIF is cyclical with Phase 4 (post-implementation learning) leading back into Phase 1. Phase 1 is the pre-implementation phase. An audit and feedback process through ERASAlberta revealed SSI rates higher than in the reported literature for gynecologic oncology patients undergoing laparotomies. The ERAS 2019 guidelines have recommended the implementation of SSIPB for gynecologic oncology patients undergoing laparotomy to help address high rates of infection [12]. We created a process map to identify key stakeholders and clarify roles and responsibilities. Phase 2 focuses on creating the structures for implementation.

The lead author met with all key stakeholders for the implementation process, this included outpatient, day surgery and word nursing managers. They in turn created educational information that was disseminated to their staff to communicate the rationale and need for the new process. A SSIPB checklist was created and placed on all eligible patient charts to remind staff to complete the checklist items. The implementation phase is Phase 3. This required sustainable educational interventions, process evaluation and feedback mechanisms. This was completed with ongoing meetings with key stakeholders that included evaluation of processes, the presentation of audit data with a plan to iteratively improve the compliance to the elements of the SSIPB. Phase 4 focuses on improving future applications. We are currently in Phase 4 for this project, as other surgical services at our hospital intend to implement the SSIPB. This phase focuses on data dissemination and the development of a toolkit built on addressing the barrier and facilitators to the SSIPB implementation.

4. Discussion

This pre- and post-intervention evaluation of a SSIPB in gynecologic oncology patients demonstrated an association of implementation with significant reductions in postoperative infections, including total SSIs and UTIs, as well as shorter length of stay. These improvements were notable as the age, ASA class, and level of surgical contamination were higher in the post-intervention period, suggesting a possible stronger effect size of the SSIPB than observed. Multivariate analysis suggested that reductions in total SSIs at 30-days after surgery seen with implementation of the SSIPB may be even greater for patients with higher BMIs. Altogether, these results provide additional evidence to support implementation of SSIPB to reduce infections and length of stay in gynecologic oncology patients.

The absolute reduction in total SSIs was 8.6% at 30-days, which is comparable to the effect size documented by other groups who implemented an SSI prevention bundle in their gynecologic oncology setting [17]. Other groups have reported a range from no effect [13] to an absolute risk reduction of 17% [10], 26% [16], 55% [15] and as high as 78% [14]. Similar to these studies, we did observe a 30-day reduction in total SSIs, overall complications and total infectious complications. The variation in effectiveness across SSI prevention bundles seen in the literature may relate to heterogeneity in the surgical approaches, patient populations, and SSI ascertainment methods seen across these reports. For example, SSI prevention bundles may reduce SSIs more for patients undergoing laparotomy [17] and therefore studies that combine laparotomy and laparoscopic procedures may see a lower effect size from implementation [15]. Most importantly, the SSI bundles tested varied importantly in their contents; bundles that reported a statistically significant reduction in SSIs focused on the pre-, intra-, and postoperative periods [14] while less effective bundles focused on only one aspect of the perioperative period [13]. These differences in SSIPB study design and implementation make it challenging to evaluate and compare the effectiveness of these bundles in different settings.

Unlike our study, many of these studies that demonstrated a reduction in SSIs did not examine for [14] or did not find a reduction in other clinical outcomes such as length of stay [15]. Due to our pre- and post-intervention study design, it is difficult to know whether the reduction in length of stay is attributable to the reduction in postoperative infections and complications or other factors. Our result is seen in a patient population where ERAS was already implemented and sustained, [20,31] and so these potential benefits are seen in addition to measures known to shorten length of stay. More rigorous studies that use synchronous control groups or other rigorous study designs are needed to determine whether these bundles reduce length of stay.

Our study has several limitations. First, using a healthcare provider completed checklist to determine which parts of the intervention were delivered as intended relies on the healthcare providers at all stages of the perioperative patient journey taking the time to complete both the activity and the checklist. An audit of the checklist revealed that the checklists were not used reliably to mark off that a task was completed. The pre-op and ward nurses recorded their interventions in the patient electronic medical record. The operating room staff incorporated the elements of the checklist automatically in the surgical instrument count and preparation for all laparotomies but again this was variably recorded on the paper checklist. The intra-operative laparotomy closure aspect of the SSIBP checklist, is completed 100% of the time and is the likely the most important contributor to the decrease in SSI between the pre-and post-intervention groups. Observational audits may more reliably determine how the intervention was delivered, though are more resource intensive. Second, establishing the diagnosis of SSI is notoriously challenging. We used the ERAS interactive audit system to define this outcome, which could result in misclassification bias [32]. However, since the nature of this misclassification is non-differential (e.g., there would be equal misdiagnosis of SSIs pre- and post-implementation), an underestimation of an effect is expected [32]. Lastly, due to the non-randomized study design and lack of a control group, we cannot say for certain whether the SSIPB was the cause of the reduction in postoperative complications, infections, and length of stay observed in this study. The multivariate regression analysis can adjust for some confounders, but a high-quality trial is likely needed to understand the effect of this intervention. Nonetheless, these results add to the growing body of literature supporting SSIPB implementation for gynecologic oncology patients.

5. Conclusion

The implementation of a SSIBP is challenging and requires the engagement of many stakeholders across outpatient and hospital settings. Despite the many barriers to implementation, the SSIBP intervention at our center successfully reduced the high rates of all surgical infections superficial, deep wound and abscess. In addition, we were able to improve other patient outcomes including length of stay without worsening re-admission rates.

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CRediT authorship contribution statement

Maede Ejaredar: Formal analysis, Writing – original draft. **Shannon M. Ruzycki:** Conceptualization, Investigation, Methodology, Supervision, Visualization, Writing – review & editing. **Tali Glazer:** Data curation, Investigation. **Pat Trudeau:** Data curation, Writing – review & editing. **Brent Jim:** Data curation, Investigation. **Gregg Nelson:** Conceptualization, Methodology, Writing – review & editing. **Anna Cameron:** Conceptualization, Data curation, Investigation, Methodology, Project administration, Supervision, Validation, Writing – review & editing.

Declaration of competing interest

The authors have no conflicts of interest related to this manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ygyno.2024.02.023.

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